

Cover Page for Statistical Analysis Plan

| | |
|--------------------------|--|
| Sponsor name: | Novo Nordisk A/S |
| NCT number | NCT03172494 |
| Sponsor trial ID: | NN9068-4148 |
| Official title of study: | A trial comparing the efficacy and safety of insulin degludec/liraglutide, insulin degludec, and liraglutide in Chinese subjects with type 2 diabetes inadequately controlled on oral antidiabetic drugs (OADs). |
| Document date: | 16 December 2019 |

16.1.9 Documentation of statistical methods

List of contents

| | |
|--------------------------------|----------------------|
| Statistical analysis plan..... | Link |
| Statistical documentation..... | Link |

*Redacted statistical analysis plan
Includes redaction of personal identifiable information only.*

Statistical Analysis Plan
Trial ID: NN9068-4148
UTN: U1111-1154-6671
EudraCT No.: N/A

CONFIDENTIAL

Date:
Version:
Status:
Page:

23 September 2019
1.0
Final
1 of 23

Novo Nordisk

Statistical Analysis Plan

Trial ID: NN9068-4148

**A trial comparing the efficacy and safety of insulin
degludec/liraglutide, insulin degludec, and liraglutide in
Chinese subjects with type 2 diabetes inadequately controlled
on oral antidiabetic drugs (OADs)**

Author

[REDACTED]

This ~~confidential~~ document is the property of Novo Nordisk. ~~No unpublished information contained herein may be disclosed without prior written approval from Novo Nordisk. Access to this document must be restricted to relevant parties.~~

Table of contents Page

| | |
|--|-----------|
| Table of contents | 2 |
| List of abbreviations | 3 |
| 1 Introduction | 5 |
| 1.1 Trial information | 5 |
| 1.2 Scope of the statistical analysis plan | 5 |
| 2 Statistical considerations | 5 |
| 2.1 Sample size calculation | 6 |
| 2.2 Definition of analysis sets | 7 |
| 2.3 Primary endpoint | 8 |
| 2.3.1 Sensitivity analysis | 9 |
| 2.4 Secondary endpoints | 10 |
| 2.4.1 Confirmatory secondary endpoints | 10 |
| 2.4.2 Supportive secondary endpoints | 12 |
| 2.4.2.1 Efficacy endpoints | 12 |
| 2.4.2.2 Safety endpoints | 14 |
| 2.5 Pharmacokinetic modelling | 20 |
| 3 Changes to the statistical analyses planned in the protocol | 21 |
| 4 References | 23 |

List of abbreviations

| | |
|-------------------|--|
| ADA | American Diabetes Association |
| AE | adverse event |
| AGI | α -glucosidase inhibitors |
| ANCOVA | analysis of covariance |
| BG | blood glucose |
| BMI | body mass index |
| CAS | completer analysis set |
| CTR | clinical trial report |
| CV | coefficient of variation |
| DBL | database lock |
| ECG | electrocardiogram |
| EOT | End of treatment |
| FAS | full analysis set |
| FDA | U.S. Food and Drug Administration |
| FPG | fasting plasma glucose |
| FU | follow-up |
| GLP-1 | glucagon-like peptide-1 |
| HbA _{1c} | glycosylated haemoglobin |
| HDL | high density lipoprotein |
| HOMA- β | homeostatic model assessment |
| IDegLira | insulin degludec/liraglutide |
| IDeg | insulin degludec |
| IDF | International Diabetes Federation |
| ITT | intention-to-treat |
| LDL | low density lipoprotein |
| LLOQ | lower limit of quantification |
| LOCF | Last Observation Carried Forward |
| MACE | major adverse cardiovascular event |
| MAP | modelling analysis plan |
| MCMC | Markov Chain Monte Carlo |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MMRM | mixed model for repeated measurements |
| OAD | oral antidiabetic drug |
| PK | pharmacokinetics |
| PP | per protocol |
| SAP | statistical analysis plan |
| SAS | safety analysis set |
| SD | standard deviation |

SU sulphonylureas
T2DM type 2 diabetes mellitus
TEAEs treatment emergent adverse events
TTT treat-to-target
TZD thiazolidinedione
UNR upper normal range
UTN Universal Trial Number
VLDL very low density lipoprotein

1 Introduction

1.1 Trial information

This is a 26 week, randomised, parallel three-arm, open-label, multi-centre, treat-to-target (TTT) confirmatory trial in Chinese subjects with T2DM inadequately controlled with metformin \pm one other OAD: α -glucosidase inhibitors (AGI), sulphonylureas (SU), glinides and thiazolidinediones (TZD). The trial is comparing efficacy and safety of insulin degludec/liraglutide (IDegLira), insulin degludec (IDeg) and liraglutide, all in combination with Metformin. For further details please see the protocol.

1.2 Scope of the statistical analysis plan

This Statistical Analysis Plan (SAP) is based on final Protocol version 5.0 (05-Dec-2016). The scope of this SAP is to add one sensitivity analysis for change from baseline in HbA_{1c} after 26 weeks of treatment and several sensitivity analyses for confirmatory secondary endpoints, and to perform other minor changes. For further details on the changes see section [3](#).

2 Statistical considerations

Novo Nordisk will analyse and report data from all sites together.

All analyses of efficacy and safety endpoints will be based on the full analysis set (FAS). The analysis of the primary endpoint and the confirmatory secondary endpoint, change from baseline in body weight after 26 weeks of treatment, will be repeated on the per-protocol (PP) analysis set and the completer analysis set (CAS) for sensitivity purposes. All efficacy endpoints will be summarised using the FAS and safety endpoints will be summarised using the safety analysis set (SAS).

The impact of protocol deviations and outliers may be investigated further in sensitivity analyses if deemed relevant.

Unless otherwise specified, all continuous measurements will be summarised descriptively at each visit by treatment using observed data. After 26 weeks of treatment, descriptive statistics will be presented based both on observed and last observation carried forward (LOCF) imputed data. Endpoints that are analysed untransformed and endpoints that are not formally analysed are summarised by the arithmetic mean, standard deviation (SD), median, and minimum and maximum value. Endpoints that are analysed log-transformed are summarised by the geometric mean and coefficient of variation (CV).

For measurements over time, mean values will be plotted to explore the trajectory over time. LOCF imputed data will be used as the basis for plotting data, if not otherwise specified. For endpoints that are analysed log-transformed, the geometric mean values will be plotted.

A standard analysis of covariance (ANCOVA) model will be applied for the continuous primary and secondary endpoints. The model includes treatment and previous OAD treatment (metformin or metformin in combination with one other OAD) as fixed factors and the corresponding baseline value as covariate. In the following, this model will be referred to as the standard ANCOVA model.

Presentation of results from a statistical analysis will include the estimated mean treatment effects (Least Square Means [LSMeans]) for absolute values and change from baseline. In addition, estimated mean treatment difference (or ratio) will be presented together with the two-sided 95% confidence interval and corresponding two-sided p-value.

Handling of missing data

The expected percentage of missing data is around 15%. In accordance with industry guidance¹ endpoints will be assessed at frequent visits and also on subjects who withdraw prematurely. This will facilitate an analysis in accordance with ITT principles. Also, the combined information on frequent outcomes and information on reason for drop-out is assumed to account for the missing data anticipated.

If an assessment has been made both at screening (Visit 1) and randomisation (Visit 2), and if not otherwise specified, the value from the randomisation visit will be used as the baseline value. If the value measured at the randomisation visit is missing and the assessment also has been made at screening, then the screening value will be used as the baseline value.

Missing values (including intermittent missing values) will be imputed using the LOCF method. Subjects without data after randomisation will be included by carrying forward their baseline value. LOCF has been a standard approach in diabetes trials for many years, and was used as the primary analysis in both IDegLira and IDeg phase 3a trials. LOCF is considered to be an appropriate method in the context of TTT trials, where subjects after withdrawal typically continue their therapy using commercially available insulin. In previous TTT trials with IDegLira and IDeg, LOCF has generally provided similar results to alternative methods applied to handle missing data, such as repeated measures models and completer analyses. In this trial, similar sensitivity analyses will be made to examine the robustness of the LOCF method. The LOCF approach will also be used to impute missing values in CAS.

2.1 Sample size calculation

The primary objective of this trial is to confirm the efficacy of IDegLira in controlling glycaemia as assessed by change from baseline in HbA_{1c} after 26 weeks of treatment vs. IDeg and liraglutide, respectively. This is done by comparing the difference in change from baseline in HbA_{1c} after 26 weeks of treatment to a non-inferiority margin of 0.4% for IDegLira vs. IDeg and to a superiority margin of 0.0% for IDegLira vs. liraglutide. The non-inferiority margin of 0.4% (absolute) was chosen in accordance with the FDA guidance¹.

A hierarchical testing procedure is applied. This is based on an a priori ordering of the null-hypotheses and testing them in this order using the two-sided 95% confidence interval approach until an insignificant result appears. Non-inferiority and superiority will thus be considered confirmed if the upper bound of the two-sided 95% confidence interval is below 0.4% and 0.0%, respectively. This is equivalent to using a one-sided test of size 2.5%, which means that the type 1 error rate is controlled at 2.5% (one-sided).

Formally, let D be the mean difference in change from baseline in HbA_{1c} . The null-hypotheses are given as:

- Non-inferiority: $H_0 D \geq 0.40\%$ against $H_A D < 0.40\%$, with an assumed mean difference in treatment of 0.0% and a standard deviation of 1.0%
- Superiority: $H_0 D \geq 0.0\%$ against $H_A D < 0.0\%$, with an assumed mean difference in treatment of -0.3% and a standard deviation of 1.0%

For evaluation of non-inferiority the PP-population is used for the sample size calculations, while the FAS is used for evaluation of superiority. It is assumed that 15% of the randomised subjects will be excluded from the PP analysis set. The above assumptions are based on experience from the phase 3a development programmes for IDegLira and IDeg. The sample size is determined using a t-statistic under the assumption of a one-sided test of size 2.5% for both the superiority and non-inferiority testing. Based on these assumptions a sample size of 720 patients results in a non-inferiority power of 98.1% and a superiority power of 90.7% i.e. the combined power for meeting the primary objective is $98.1\% * 90.7\% = 89.0\%$. A sample size of 720 patients with a 15% drop-out rate and a 2:1:1 randomisation results in 306 PP patients in the IDegLira arm.

2.2 Definition of analysis sets

The following analysis sets are defined in accordance with the ICH-E9 guidance².

- **Full Analysis Set (FAS):** includes all randomised subjects. In exceptional cases, subjects may be eliminated from the full analysis set. In such cases the elimination will be justified and documented. The statistical evaluation of the FAS will follow the intention-to-treat (ITT) principle and subjects will contribute to the evaluation “as randomised”.
- **Per-Protocol (PP) analysis set:** includes all subjects in the FAS who fulfils the following criteria:
 - Have not violated any inclusion criteria
 - Have not fulfilled any exclusion criteria
 - Have a non-missing HbA_{1c} at screening or randomisation
 - Have at least one non-missing HbA_{1c} after 12 weeks of exposure
 - Have at least 12 weeks of exposure

Subjects will contribute to the evaluation “as treated”.

- **Safety Analysis Set (SAS):** includes all subjects receiving at least one dose of the investigational product or comparator. Subjects in the safety set will contribute to the evaluation “as treated”.
- **Completer Analysis Set (CAS):** includes all randomised subjects who have completed the trial. Subjects in the completer analysis set will contribute to the evaluation “as randomised”.

Randomised subjects who are lost to follow up and where no exposure information of the investigational product or comparators is available after randomisation will be handled as unexposed.

Before data are released for statistical analysis, a review of all data will take place to identify protocol deviations that could potentially affect the results. Any decision to exclude any subject or observation from the statistical analysis is the joint responsibility of the members of the study group. The subjects or observations to be excluded, and the reasons for their exclusion must be documented and signed by those responsible before database lock. The subjects and observations excluded from analysis sets, and the reason for this, will be described in the clinical trial report.

2.3 Primary endpoint

The primary endpoint is defined as change from baseline in HbA_{1c} after 26 weeks of treatment.

The change from baseline in HbA_{1c} after 26 weeks of treatment will be analysed using an ANCOVA model with treatment and previous OAD treatment (metformin ± one other OAD) as fixed factors and baseline HbA_{1c} as covariate. Missing values after 26 weeks of treatment will be imputed applying LOCF using HbA_{1c} values at and after baseline.

Non-inferiority of IDegLira vs. IDeg will be considered as confirmed if the 95% confidence interval for the mean treatment difference lies entirely below 0.4%; equivalent to a one-sided test with significance level of 2.5%. Non-inferiority will be investigated on the FAS. Sensitivity analysis will be performed on the PP analysis set.

Superiority of IDegLira vs. liraglutide will be considered as confirmed if the 95% confidence interval for the mean treatment difference for change from baseline in HbA_{1c} lies entirely below 0.0%; equivalent to a one-sided test with significance level of 2.5%. Conclusion of superiority will be based on FAS. The primary objective will be fulfilled only if both non-inferiority of IDegLira vs. IDeg and superiority of IDegLira vs. liraglutide are confirmed.

In addition to the non-inferiority margin of 0.4% the upper bound of the confidence interval for the mean treatment difference of IDegLira vs. IDeg will also be compared to a 0.0% margin. This comparison is not part of the hierarchical testing procedure.

2.3.1 Sensitivity analysis

The primary analysis will be repeated on the PP analysis set and the CAS as sensitivity analysis. Furthermore, sensitivity analysis will be performed on FAS using the mixed model for repeated measurement (MMRM) to evaluate the sensitivity of using LOCF. All HbA_{1c} values available post baseline at scheduled measurement times will be analysed in a linear mixed normal model using an unstructured residual covariance matrix for HbA_{1c} measurements within the same subject. The model will include treatment, visit, and previous OAD treatment as fixed factors and baseline HbA_{1c} as covariate. Interactions between visit and all factors and the covariate are also included in the model.

Further, a pattern mixture model approach, mimicking an ITT scenario will be applied. The imputation will follow the hypothesis being tested. i.e., when deriving the IDegLira vs. IDeg contrast the imputation in the IDegLira arm will be based on IDeg values, whereas for the IDegLira vs. liraglutide contrast the imputation in the IDegLira arm will be based on liraglutide values. Furthermore, 0.4% (absolute) will be added to the imputed values in the IDegLira arm for the non-inferiority comparison against IDeg to mimic a scenario where subjects discontinued from IDegLira treatment are assumed to be switched to a treatment inferior to IDeg. In other words: two imputation datasets will be made, one for IDegLira and IDeg and one for IDegLira and liraglutide. In the analyses, depending on the hypothesis being tested, the respective imputation dataset will be used and the third arm (from the other imputation dataset) will be kept in the model. The imputations for each hypothesis will be done as follows:

- In the first step intermittent missing values are imputed using a Markov Chain Monte Carlo (MCMC) method, in order to obtain a monotone missing data pattern. This imputation is done for each treatment group separately and 1000 copies of the dataset will be generated.
- In the second step, for each of the 1000 copies of the dataset, an analysis of variance model with previous OAD treatment as a fixed factor, and baseline HbA_{1c} as a covariate is fitted to the change in HbA_{1c} from baseline to 4 weeks (Visit 6) for a given comparator group only. The estimated parameters, and their variances, from this model are used to impute missing values at 4 weeks for subjects in the comparator and IDegLira treatment groups, based on previous OAD treatment and HbA_{1c} at baseline.
- In the third step, for each of the 1000 copies of the dataset, missing HbA_{1c} values at 8 weeks (Visit 10) are imputed in the same way as for 4 weeks. Now the imputations are based on an analysis of variance model with the same factors and the HbA_{1c} values at baseline and 4 weeks as covariates, fitted to the comparator group.
- This stepwise procedure is then repeated sequentially over the available planned visits, adding one visit in each step until the last planned visit at 26 weeks (Visit 28).

- For the comparison against IDeg, for each subject discontinued from treatment in the IDegLira treatment group, a value of 0.4% (absolute; the non-inferiority limit) is added to the change in HbA_{1c} at 26 weeks.

For each of the complete data sets, the change from baseline to 26 weeks is analysed using an analysis of variance model with treatment and previous OAD treatment as fixed factors and baseline HbA_{1c} value as a covariate.

The estimates and standard deviations for the 1000 data sets are pooled to one estimate and associated standard deviation using Rubin's rule³. From these pooled estimates the confidence interval for the treatment differences and the associated p-value are calculated.

The results of sensitivity analyses will be compared to the result of the standard ANCOVA method using LOCF for imputation of missing data. Any marked difference between the MMRM, the pattern mixture approach and ANCOVA LOCF approach regarding the estimated treatment difference will be commented upon in the CTR.

2.4 Secondary endpoints

2.4.1 Confirmatory secondary endpoints

The following two confirmatory endpoints will be tested for superiority of IDegLira vs. IDeg.

- Change from baseline in body weight after 26 weeks of treatment.
- Number of treatment emergent severe or BG confirmed hypoglycaemic episodes during 26 weeks of treatment.

The tests for superiority of the confirmatory secondary endpoints will be based on the FAS and will only be carried out if non-inferiority of IDegLira vs. IDeg and superiority of IDegLira vs. liraglutide with regards to the primary endpoint are confirmed.

In order to control the overall type I error on a 2-sided 5% level with regards to the secondary endpoints, a hierarchical testing procedure will be used. If superiority is confirmed with respect to change from baseline in body weight after 26 weeks of treatment the number of treatment emergent severe or BG confirmed hypoglycaemic episodes during 26 weeks of treatment will be tested for superiority.

Superiority for change from baseline in body weight will be considered confirmed if the upper bound of the two-sided 95% confidence interval for the estimated mean treatment difference (IDegLira minus IDeg) is strictly below zero or equivalently if the p-value for the one-sided test of

$$H_0 D \geq 0.0 \text{ against } H_A D < 0.0,$$

is less than 2.5%, where D is the treatment difference.

The change from baseline in body weight after 26 weeks of treatment will be analysed using an ANCOVA model with treatment and previous OAD treatment (metformin ± one other OAD) as fixed factors and baseline weight as covariate.

Similar sensitivity analyses as specified for the primary endpoint (ANCOVA on the PP analysis set and CAS; MMRM; the pattern mixture model similar to that described for HbA_{1c}, but without added non-inferiority penalty) will be performed.

Superiority for hypoglycaemic episodes will be considered confirmed if the upper bound of the two-sided 95% confidence interval for the estimated mean treatment ratio (IDegLira vs. IDeg) is strictly below one or equivalently if the p-value for the one-sided test of

$$H_0 \text{ RR} \geq 1.0 \text{ against } H_A \text{ RR} < 1.0,$$

is less than 2.5%, where RR is the treatment rate ratio.

Number of treatment emergent severe or BG confirmed hypoglycaemic episodes during 26 weeks of treatment will be analysed using a negative binominal regression model with a log-link function and the logarithm of the time period in which a hypoglycaemic episode is considered treatment emergent as offset. The model will include treatment and previous OAD treatment as fixed factors.

As a sensitivity analysis, for withdrawn subjects, the number of episodes in the missing period (time of withdrawal to planned treatment emergent period [max of 27 weeks and longest treatment emergent time observed in the trial, in all 3 treatment arms]) will be imputed using a multiple imputation technique⁴. The first step (getting samples from the posterior distribution) is done once, for all three arms together. In the second step, the imputation will follow the hypothesis being tested. When deriving the IDegLira vs. IDeg treatment ratio the imputation will be based on an assumption that the event rates before and after withdrawal in both arms correspond to the event rate in the IDeg group. Similarly for the IDegLira vs liraglutide treatment ratio, the event rate before and after withdrawal is assumed to correspond to the event rate in the liraglutide arm. In other words: two imputation datasets will be made, one for IDegLira and IDeg and one for IDegLira and liraglutide. In the analyses, depending on the hypothesis being tested, the respective imputation dataset will be used and the third arm (from the other imputation dataset) will be kept in the model.

The imputation will be done as follows:

- As a first step, a Bayes negative binomial model with the same fixed factors used in the original confirmatory analysis model is fitted to the event rate data to obtain the posterior distribution of model parameters.

- In the second step, based on the estimated parameters for comparator in this model, the number of events in the missing period is imputed for all withdrawn subjects, i.e. pre and post withdrawal event rates in the conditional distribution used for imputation are as for a given comparator. Multiple copies (1000 copies) of a complete data set are generated by sampling from the estimated distribution.

For each of the complete data sets, the number of events is analysed using a negative binomial model including the same fixed factors used in the original model.

The estimates and standard deviations for the 1000 data sets are pooled to one estimate and associated standard deviation using Rubin's rule³. From these pooled estimates the confidence interval for the treatment ratio and the associated p-value are calculated.

Subjects with missing exposure time will not contribute to the analysis.

2.4.2 Supportive secondary endpoints

2.4.2.1 Efficacy endpoints

In the following the statistical models will be fitted to all data simultaneously (all treatment groups) and from this model the treatment differences for IDegLira vs. IDeg and IDegLira vs. liraglutide will be estimated. For insulin dose, the model will be fitted only to data from the IDegLira and IDeg treatment groups.

Insulin dose after 26 weeks of treatment

The actual daily insulin dose after 26 weeks of treatment will be analysed using an ANCOVA model including treatment and previous OAD treatment as fixed factors and baseline HbA_{1c} value as covariate.

Responder for HbA_{1c} after 26 weeks of treatment

Two dichotomous endpoints (responder/non-responder) will be defined based on whether a subject has met a specific target level after 26 weeks of treatment:

- ADA HbA_{1c} target (HbA_{1c} < 7.0%)
- International Diabetes Federation (IDF) HbA_{1c} target (HbA_{1c} ≤ 6.5%)

Analysis of each of the two responder endpoints will be based on a logistic regression model with treatment and previous OAD treatment as fixed factors and baseline HbA_{1c} value as a covariate.

HbA_{1c} responder endpoints without weight gain

Responder for HbA_{1c} without weight gain after 26 weeks of treatment will be defined as HbA_{1c} < 7.0% or ≤ 6.5% at end of treatment and change from baseline in body weight below or

equal to zero. Analysis of each of the two responder endpoints will be based on a logistic regression model with treatment and previous OAD treatment as fixed factors and baseline HbA_{1c} and body weight values as covariates.

HbA_{1c} responder endpoints without hypoglycaemic episodes

Responder for HbA_{1c} without hypoglycaemic episodes after 26 weeks of treatment will be defined as HbA_{1c} < 7.0% or ≤ 6.5% at end of treatment and without severe or BG confirmed episodes during the last 12 weeks of treatment. Analysis of each of the two responder endpoints will be based on a logistic regression model with treatment and previous OAD treatment as fixed factors and baseline HbA_{1c} values as a covariate.

HbA_{1c} responder endpoints without hypoglycaemic episodes and weight gain

Responder for HbA_{1c} without hypoglycaemic episodes and weight gain after 26 weeks of treatment will be defined as HbA_{1c} < 7.0% or ≤ 6.5% at end of treatment, without severe or BG confirmed episodes during the last 12 weeks of treatment, and change from baseline in body weight below or equal to zero. Analysis of each of the two responder endpoints will be based on a logistic regression model with treatment and previous OAD treatment as fixed factors and baseline HbA_{1c} and body weight values as covariates.

Fasting plasma glucose (FPG)

Change from baseline in FPG after 26 weeks of treatment will be analysed using the standard ANCOVA model.

Waist circumference

Change from baseline in waist circumference after 26 weeks of treatment will be analysed using the standard ANCOVA model.

Beta-cell function (fasting insulin, fasting C-peptide, fasting glucagon, and HOMA-β)

In addition to fasting insulin, fasting C-peptide, and fasting glucagon, one derived parameter will be calculated; beta-cell function (HOMA-β). The calculation of the HOMA endpoint will be done as follows:

- Beta-cell function (%) = $20 \cdot \text{fasting insulin}[\mu\text{U/mL}] / (\text{FPG}[\text{mmol/L}] - 3.5)$

These endpoints after 26 weeks of treatment will be analysed separately using the standard ANCOVA model. In these statistical analyses the endpoint will be log-transformed and so will the baseline covariate.

Fasting lipid profile

Cholesterol, LDL cholesterol, HDL cholesterol, VLDL cholesterol, triglycerides, and free fatty acids after 26 weeks of treatment will be analysed separately using the standard ANCOVA model. In these statistical analyses the endpoint will be log-transformed and so will the baseline covariate.

Self-measured plasma glucose 9-point profile

Three endpoints from the 9-point profile will be defined:

- 9-point profile
- Mean of the 9-point profile, defined as the area under the profile (calculated using the trapezoidal method) divided by the measurement time
- Post-prandial plasma glucose increments (from before meal to 90 min after for breakfast, lunch and dinner). The mean increment over all meals will be derived as the mean of all available meal increments

A mixed effect model will be fitted to the 9-point profile data. The model will include treatment, previous OAD treatment, time, interaction between treatment and time, and interaction between previous OAD treatment and time as fixed factors, and subject as random effect, where measurements within subjects will be assumed correlated with a compound symmetry covariance matrix. From the model mean profile by treatment and relevant treatment differences will be estimated and explored.

Change from baseline after 26 weeks of treatment in mean of the 9-point profile and post-prandial increment endpoints will be analysed separately using the standard ANCOVA model.

2.4.2.2 Safety endpoints

Adverse events

AEs will be coded using the most recent version of the Medical Dictionary for Regulatory Activities (MedDRA) coding.

A treatment emergent adverse event (TEAE) is defined as an event that has onset date on or after the first day of exposure to randomised treatment and no later than seven days after the last day of randomised treatment. If the event has onset date before the first day of exposure on randomised treatment and increases in severity during the treatment period and until 7 days after the last drug date, then this event should also be considered as a TEAE. Major adverse cardiovascular events (MACEs, defined as all cardiovascular deaths, non-fatal myocardial infarctions and non-fatal strokes) are considered treatment-emergent until 30 calendar days after the last dose of trial product.

TEAEs are summarised descriptively, whereas non-TEAEs are presented in listings. TEAE data will be displayed in terms of the number of subjects with at least one event (N), the percentage of

subjects with at least one event (%), the number of events (E) and the event rate per 100 years of exposure (R).

Summaries of TEAEs and of serious TEAEs will be presented as an overview including all AEs, AEs by seriousness, AEs by severity, AEs by relation to treatment, technical complaint AEs and AEs by outcome (including deaths).

Furthermore, summary tables based on system organ class and preferred terms are made for:

- All TEAEs
- TEAEs leading to withdrawal
- Serious TEAEs
- Possibly or probably related TEAEs
- Severe, moderate and mild TEAEs
- TEAEs reported by safety areas of interest
- TEAEs with preferred term that are experienced by at least 5% of the subjects in any treatment arm or by at least 5% of all subjects

A listing for non-TEAEs with onset date before the first day of exposure to randomised treatment will be presented. A listing will also be presented for non-TEAEs collected after the treatment emergent period according to the definition of TEAE.

Classification of Hypoglycaemia

Treatment emergent: hypoglycaemic episodes will be defined as treatment emergent if the onset of the episode occurs on or after the first day of trial product administration, and no later than 7 days after the last day on trial product.

Nocturnal hypoglycaemic episodes: are episodes with time of onset between 00:01 and 05.59 both inclusive.

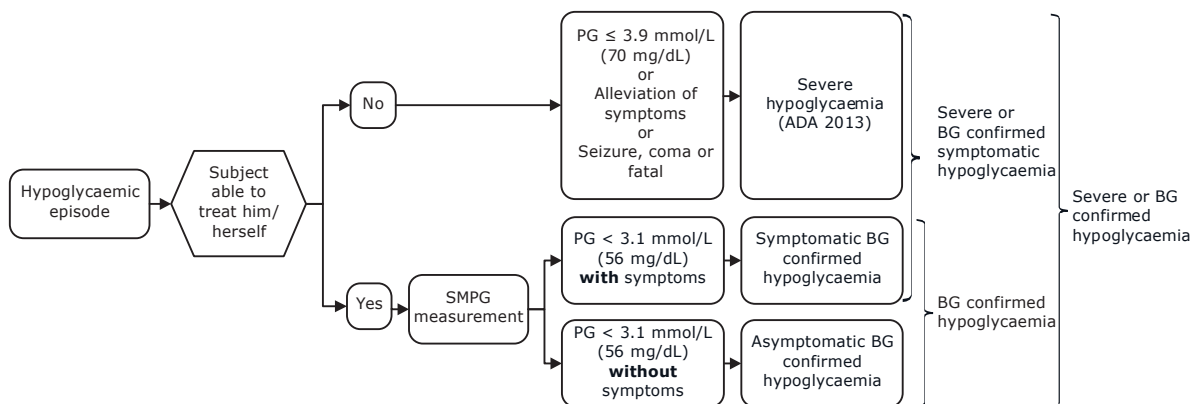
Hypoglycaemic episodes are classified according to the Novo Nordisk classification of hypoglycaemia (see [Figure 2-1](#)) and the ADA classification of hypoglycaemia (see [Figure 2-2](#)).

Novo Nordisk classification of hypoglycaemia

In normal physiology, symptoms of hypoglycaemia occur below a plasma glucose level of 3.1 mmol/L.⁵ Therefore, Novo Nordisk has included hypoglycaemia with plasma glucose levels below this cut-off point in the definition of BG confirmed hypoglycaemia.

Novo Nordisk uses the following classification (see [Figure 2-1](#)) in addition to the ADA classification (see [Figure 2-2](#)):

- Severe or BG confirmed symptomatic hypoglycaemia: An episode that is severe according to the ADA classification⁶ or BG confirmed by a plasma glucose value <3.1 mmol/L **with** symptoms consistent with hypoglycaemia.
- Severe or BG confirmed hypoglycaemia: An episode that is severe according to the ADA classification⁶ or BG confirmed by a plasma glucose value <3.1 mmol/L **with or without** symptoms consistent with hypoglycaemia.



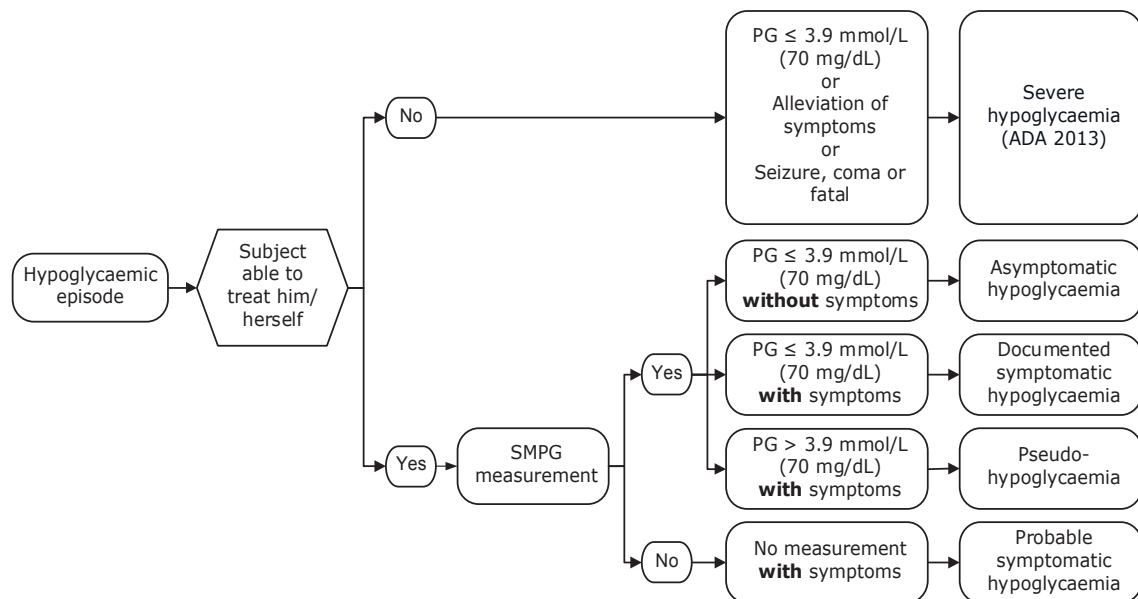
Note: Glucose measurements are performed with capillary blood calibrated to plasma equivalent glucose values

BG: blood glucose PG: plasma glucose SMPG: Self-measured plasma glucose

Figure 2–1 Novo Nordisk classification of hypoglycaemia

ADA classification of hypoglycaemia⁶

- Severe hypoglycaemia: An episode requiring assistance of another person to actively administer carbohydrate, glucagon, or take other corrective actions. Plasma glucose concentrations may not be available during an event, but neurological recovery following the return of plasma glucose to normal is considered sufficient evidence that the event was induced by a low plasma glucose concentration.
- Asymptomatic hypoglycaemia: An episode not accompanied by typical symptoms of hypoglycaemia, but with a measured plasma glucose concentration ≤ 3.9 mmol/L.
- Documented symptomatic hypoglycaemia: An episode during which typical symptoms of hypoglycaemia are accompanied by a measured plasma glucose concentration ≤ 3.9 mmol/L.
- Pseudo-hypoglycaemia: An episode during which the person with diabetes reports any of the typical symptoms of hypoglycaemia with a measured plasma glucose concentration > 3.9 mmol/L but approaching that level.
- Probable symptomatic hypoglycaemia: An episode during which symptoms of hypoglycaemia are not accompanied by a plasma glucose determination but that was presumably caused by a plasma glucose concentration ≤ 3.9 mmol/L.



Note: Glucose measurements are performed with capillary blood calibrated to plasma equivalent glucose values

PG: plasma glucose SMPG: Self-measured plasma glucose

Figure 2–2 ADA classification of hypoglycaemia

Data on treatment emergent hypoglycaemic episodes are presented in terms of the number of subjects with at least one event (N), the percentage of subjects with at least one event (%), the number of events (E) and the event rate per 100 years (R).

Separate summaries are made for severe or BG confirmed hypoglycaemic episodes, severe or BG confirmed symptomatic hypoglycaemic episodes, nocturnal severe or BG confirmed hypoglycaemic episodes, nocturnal severe or BG confirmed symptomatic hypoglycaemic episodes and the ADA classification of hypoglycaemia.

The number of hypoglycaemic episodes during 26 weeks of treatment will be analysed separately for each endpoint using a negative binomial regression model with a log-link function and the logarithm of the time period in which a hypoglycaemic episode is considered treatment emergent as offset. The model will include treatment and previous OAD treatment at fixed factors.

Pulse

Change from baseline in pulse after 26 weeks of treatment will be analysed using the standard ANCOVA model.

Systolic and diastolic blood pressure

Change from baseline in systolic and diastolic blood pressure after 26 weeks of treatment will be analysed using the standard ANCOVA model.

Clinical evaluations (physical examination, eye examination and ECG)

Eye examination (dilated funduscopy/fundus photography) and ECG findings will be summarised descriptively, including:

- Summaries
- The change from baseline after 26 weeks of treatment

Any clinically significant deterioration of a pre-existing condition after the screening visit, as well as any new clinically significant findings will be recorded as adverse events.

Laboratory assessments

All laboratory parameters will be summarised descriptively. The following tables will be presented based on both observed and LOCF imputed data:

- Shift tables from baseline to after 26 weeks of treatment.
- Proportion of subjects with measurements outside reference range by treatment and week.

Laboratory values for lipase, amylase and calcitonin will be presented graphically as box plots by treatment and week.

For each laboratory parameter, individual values outside the reference ranges (abnormal values) will be listed.

For lipase and amylase the following rule applies in the evaluation of the result:

- If the amylase or lipase baseline (at screening) value is $> 3 \times \text{UNR}$ the information will be recorded as medical history for that subject.

Calcitonin

The purpose of the calcitonin analysis is to evaluate longitudinal changes in calcitonin, with main focus on subjects who develop persistently high levels of calcitonin during the trial.

Calcitonin will be displayed in terms of the number of subjects (N), the percentage of subjects (%) and the event rate per 100 years of exposure (R). The following criteria are defined for tabulations:

- **Persistent (all post baseline measurements)**
 - From $< \text{UNR}$ to persistently $\geq \text{UNR}$
 - From $< \text{UNR}$ to persistently $\geq 1.5 \text{ UNR}$
 - From $< \text{UNR}$ to persistently $\geq 20 \text{ ng/L}$
 - From $< \text{UNR}$ to persistently $\geq 50 \text{ ng/L}$
 - From $< 20 \text{ ng/L}$ to persistently $\geq 20 \text{ ng/L}$
 - From $< 50 \text{ ng/L}$ to persistently $\geq 50 \text{ ng/L}$
- **Incidental (at least one post baseline measurements)**
 - From $< \text{UNR}$ to $\geq \text{UNR}$
 - From $< \text{UNR}$ to $\geq 1.5 \text{ UNR}$
 - From $< \text{UNR}$ to $\geq 20 \text{ ng/L}$
 - From $< \text{UNR}$ to $\geq 50 \text{ ng/L}$
 - From $< 20 \text{ ng/L}$ to $\geq 20 \text{ ng/L}$
 - From $< 50 \text{ ng/L}$ to $\geq 50 \text{ ng/L}$

The distribution of all calcitonin measurements across treatment groups and time will be shown with box plots and corresponding cumulative plots for actual levels of calcitonin and change from baseline. The plots will be presented by treatment group at EOT using LOCF imputed values and within treatment group by week. Plots will be done by each gender, separately.

Summaries tables of calcitonin continuous measurements, will include number and percentage of observations $<$ and \geq LLOQ, minimum, Q25, median, Q75 and maximum. Summaries will be presented for all subjects and by gender.

Longitudinal changes for subjects with calcitonin levels ≥ 20 ng/l will be plotted (longitudinal plots). The plots will be done by treatment and gender. They will be done for subjects in the persistent and incidental categories, separately.

A listing of subjects with at least one post baseline value ≥ 20 ng/l will be done. The listing will include age, gender, calcitonin measurements over time and AE history (including preferred term, onset and stop dates).

Urinalysis

Categorical urinalysis parameters will be summarised descriptively by:

- Shift from baseline to EOT (using the number of subjects in the different categories).
- Subjects with at least one post baseline measurement outside reference range will be listed.

Insulin and GLP-1 antibodies

Insulin antibodies (IDeg specific, cross-reacting to human insulin and total) will be summarised with arithmetic mean, standard deviation (SD), median, and minimum and maximum value by treatment and treatment week, and their mean over time will be plotted. Correlations will be explored graphically as follows. Insulin antibodies (IDeg specific, cross-reacting to human insulin and total) will be plotted against HbA_{1c} after 26 weeks, HbA_{1c} change from baseline after 26 weeks, and dose after 26 weeks. Change from baseline to FU1 in insulin antibodies (IDeg specific, cross-reacting to human insulin and total) will be plotted against HbA_{1c} after 26 weeks, HbA_{1c} change from baseline after 26 weeks, and dose after 26 weeks.

GLP-1 antibodies (liraglutide specific, cross-reacting to native GLP-1, liraglutide *in vitro* neutralising and *in vitro* neutralising to native GLP-1) will be summarised by number of subjects (N) and percentage of subjects (%) with positive and negative samples.

2.5 Pharmacokinetic modelling

Population pharmacokinetic analysis

The objective for this analysis is to compare the pharmacokinetics of IDegLira and its individual components at clinically relevant doses during 26 weeks of treatment. Furthermore, dose-proportionality of IDeg and liraglutide exposures following doses of IDegLira will be evaluated and the effects of pre-specified covariates on exposures of IDeg and liraglutide will be investigated. Pharmacokinetic samples for IDeg and liraglutide sampled at site visits will be included in the analysis. No pre-defined time of day is specified for the sampling, but the date and exact clock time of sampling will be recorded by the investigator. The subjects must be instructed to write in their

diary the date, exact clock time, dose, and injection site of the previous three days of dosing as well as the dose on the day of the visit, if taken before PK blood sampling.

The population PK analysis will be performed by the Quantitative Clinical Pharmacology Department at Novo Nordisk. A more technical and detailed elaboration of the population PK analysis will be given in the modelling analysis plan (MAP) which will be finalised before DBL.

The pre-specified analysis will explore the effects of covariates on the IDeg and liraglutide exposure. The structural models and covariate relationships will be predefined in detail in the MAP. In brief, previously developed population PK models for IDeg and liraglutide will be used. For both PK models, the absorption rate constant (K_a) will be fixed and the apparent clearance (CL/F) and the apparent volume of distribution (V_d/F) will be estimated.

The covariates of interest will be evaluated using criteria which will be specified in the MAP.

The following covariates will be tested on the apparent clearance (CL/F):

- Dose
- Treatment (IDegLira, IDeg, liraglutide)
- Injection site area (Abdomen, Upper arm, Thigh)
- Body weight
- Age group (< 65 , ≥ 65 years)
- Gender (Male/Female)

For the categorical variables, it is a requirement to have at least 20 subjects in each category.

Exposure-response analysis

The exposure-response relationship will be investigated for selected response variables, such as HbA_{1c} . Individual drug concentration data will be tabulated in the CTR.

The population PK and exposure-response analyses will be reported in a separate modelling report, which will not be a part of the CTR.

3 Changes to the statistical analyses planned in the protocol

- Additional sensitivity analysis was added, using the pattern mixture model, in order to evaluate the sensitivity of using LOCF for primary endpoint, change from baseline in HbA_{1c} after 26 weeks of treatment.
- Sensitivity analyses for confirmatory secondary endpoint, change from baseline in body weight after 26 weeks of treatment, were added to evaluate the sensitivity of using LOCF.

- Sensitivity analysis for confirmatory secondary endpoint, number of treatment emergent severe or BG confirmed hypoglycaemic episodes during 26 weeks of treatment, was added to evaluate the sensitivity of the analysis specified in the protocol.
- A minor correction regarding the analysis model for the supportive secondary endpoint of 9-point self-measured plasma glucose was made (baseline value was removed from the model and interaction between previous OAD and time was added).
- Box plots will only be presented for relevant laboratory assessments: lipase, amylase and calcitonin.
- Listings deemed unnecessary were removed: antibody measurements, physical examination findings.
- Minor editorial changes were made, and clarifications were added where considered relevant.

4 References

1. Food and Drug Administration, CDER. Guidance for Industry. Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention, Draft Guidance. February 2008.
2. ICH Harmonised Tripartite Guideline. Statistical Principles for Clinical Trials E9, Current Step 4 version. 05 Feb 1998.
3. Little RJA, Rubin DB. Statistical analysis with missing data. New York: Wiley. 1987. xiv, 278 p.
4. Keene ON, Roger JH, Hartley BF, Kenward MG. Missing data sensitivity analysis for recurrent event data using controlled imputation. *Pharmaceutical Statistics*. 2014;13(4):258-64.
5. Schwartz NS, Clutter WE, Shah SD, Cryer PE. Glycemic thresholds for activation of glucose counterregulatory systems are higher than the threshold for symptoms. *J Clin Invest*. 1987;79(3):777-81.
6. Seaquist ER, Anderson J, Childs B, Cryer P, Dagogo-Jack S, Fish L, et al. Hypoglycemia and diabetes: a report of a workgroup of the American Diabetes Association and the Endocrine Society. *Diabetes Care*. 2013;36(5):1384-95.

Table of contents

| | Page |
|--|-------------|
| 1: Actual daily total insulin dose after 26 weeks of treatment - supportive statistical analysis - full analysis set..... | 3 |
| 2: HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set..... | 5 |
| 3: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set..... | 15 |
| 4: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set..... | 25 |
| 5: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set..... | 35 |
| 6: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set..... | 59 |
| 7: HbA1c after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set..... | 87 |
| 8: Responder for HbA1c treatment target - supportive statistical analysis - full analysis set..... | 97 |
| 9: Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes - supportive statistical analysis - full analysis set..... | 101 |
| 10: Responder for HbA1c treatment target without weight gain - supportive statistical analysis - full analysis set..... | 105 |
| 11: Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes and weight gain - supportive statistical analysis - full analysis set..... | 109 |
| 12: Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set..... | 113 |
| 13: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set..... | 123 |
| 14: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set..... | 133 |
| 15: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set..... | 143 |
| 16: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set..... | 167 |
| 17: Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set..... | 195 |
| 18: Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set..... | 200 |
| 19: 9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set..... | 209 |

| | |
|--|-----|
| 20: Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set..... | 277 |
| 21: Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set | 287 |
| 22: Fasting insulin after 26 weeks of treatment - supportive statistical analysis - full analysis set..... | 327 |
| 23: Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set | 330 |
| 24: Fasting glucagon after 26 weeks of treatment - supportive statistical analysis - full analysis set | 336 |
| 25: HOMA-B after 26 weeks of treatment - supportive statistical analysis - full analysis set..... | 339 |
| 26: HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set | 342 |
| 27: LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set | 348 |
| 28: VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set..... | 354 |
| 29: Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set | 360 |
| 30: Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set..... | 366 |
| 31: Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set | 372 |
| 32: Hypoglycaemic episodes - treatment emergent - confirmatory statistical analysis - full analysis set | 378 |
| 33: Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set | 381 |
| 34: Hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set | 389 |
| 35: Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set..... | 392 |
| 36: Pulse after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set..... | 398 |
| 37: Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set..... | 403 |
| 38: Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set..... | 408 |

Statistical documentation

1: Actual daily total insulin dose after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=TOTDDAC

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 2 | 1 2 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 6 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 530 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 540 |
| Number of Observations Used | 530 |
| Number of Observations Not Used | 10 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 156.79 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4173.3 |
| AIC (Smaller is Better) | 4175.3 |
| AICC (Smaller is Better) | 4175.3 |
| BIC (Smaller is Better) | 4179.6 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 9.5426 | 5.5886 | 526 | 1.71 | 0.0883 | 0.05 |
| trtpn | | 1 | -5.4917 | 1.1603 | 526 | -4.73 | <.0001 | 0.05 |
| trtpn | | 2 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.8080 | 1.1686 | 526 | -0.69 | 0.4896 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| HBA1CBL | | | 2.5256 | 0.6569 | 526 | 3.84 | 0.0001 | 0.05 |

Actual daily total insulin dose after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=TOTDDAC

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | -1.4362 | 20.5213 |
| trtpn | | 1 | -7.7712 | -3.2123 |
| trtpn | | 2 | | |
| PREOAD2 | Metformin | | -3.1038 | 1.4877 |
| PREOAD2 | Metformin + OAD | | | |
| HBA1CBL | | | 1.2352 | 3.8160 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 1 | 526 | 22.40 | <.0001 |
| PREOAD2 | 1 | 526 | 0.48 | 0.4896 |
| HBA1CBL | 1 | 526 | 14.78 | 0.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 24.6139 | 0.6640 | 526 | 37.07 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 30.1057 | 0.9504 | 526 | 31.68 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 23.3095 | 25.9184 | 4.894E10 | 1.328E10 | 1.804E11 |
| trtpn | LSMeans, IDeg | 28.2385 | 31.9728 | 1.188E13 | 1.836E12 | 7.684E13 |

Least Squares Means Estimate

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -5.4917 | 1.1603 | 526 | -4.73 |

Least Squares Means Estimate

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -7.7712 | -3.2123 | 0.004121 |

Least Squares Means Estimate

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.000422 | 0.04027 |

2: HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.5548 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1635.3 |
| AIC (Smaller is Better) | 1637.3 |
| AICC (Smaller is Better) | 1637.3 |
| BIC (Smaller is Better) | 1641.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.5634 | 0.2879 | 715 | 15.85 | <.0001 | 0.05 |
| TRTPN | | 1 | -0.6283 | 0.06796 | 715 | -9.25 | <.0001 | 0.05 |
| TRTPN | | 2 | -0.03366 | 0.07869 | 715 | -0.43 | 0.6690 | 0.05 |
| TRTPN | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3922 | 0.05944 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.3338 | 0.03413 | 715 | 9.78 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 3.9982 | 5.1287 |
| TRTPN | | 1 | -0.7618 | -0.4949 |
| TRTPN | | 2 | -0.1882 | 0.1208 |
| TRTPN | | 3 | | |
| PREOAD2 | Metformin | | -0.5089 | -0.2755 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2668 | 0.4008 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| TRTPN | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 95.66 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| TRTPN | LSMeans, IDegLira | WORK.ADATA2 | 6.5559 | 0.03921 | 715 | 167.18 | <.0001 | 0.05 |
| TRTPN | LSMeans, IDeg | WORK.ADATA2 | 7.1506 | 0.05574 | 715 | 128.29 | <.0001 | 0.05 |
| TRTPN | LSMeans, Lira | WORK.ADATA2 | 7.1842 | 0.05552 | 715 | 129.40 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| TRTPN | LSMeans, IDegLira | 6.4789 | 6.6329 | 703.38 | 651.26 | 759.68 |
| TRTPN | LSMeans, IDeg | 7.0412 | 7.2600 | 1274.85 | 1142.71 | 1422.27 |
| TRTPN | LSMeans, Lira | 7.0752 | 7.2933 | 1318.50 | 1182.33 | 1470.34 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| TRTPN | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.5947 | 0.06819 | 715 | -8.72 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| TRTPN | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -0.7286 | -0.4608 | 0.5517 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| TRTPN | Treatment contrast, IDegLira - IDeg | 0.4826 | 0.6308 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| TRTPN | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -0.6283 | 0.06796 | 715 | -9.25 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| TRTPN | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -0.7618 | -0.4949 | 0.5335 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| TRTPN | Treatment contrast, IDegLira - Lira | 0.4668 | 0.6096 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 66.2773 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5060.0 |
| AIC (Smaller is Better) | 5062.0 |
| AICC (Smaller is Better) | 5062.0 |
| BIC (Smaller is Better) | 5066.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 34.2233 | 2.3673 | 715 | 14.46 | <.0001 | 0.05 |
| TRTPN | | 1 | -6.8678 | 0.7428 | 715 | -9.25 | <.0001 | 0.05 |
| TRTPN | | 2 | -0.3679 | 0.8601 | 715 | -0.43 | 0.6690 | 0.05 |
| TRTPN | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.2869 | 0.6497 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.3338 | 0.03413 | 715 | 9.78 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 29.5757 | 38.8709 |
| TRTPN | | 1 | -8.3262 | -5.4094 |
| TRTPN | | 2 | -2.0566 | 1.3207 |
| TRTPN | | 3 | | |
| PREOAD2 | Metformin | | -5.5625 | -3.0113 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2668 | 0.4008 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| TRTPN | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 95.66 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| TRTPN | LSMeans, IDegLira | WORK.ADATA2 | 48.1560 | 0.4286 | 715 | 112.35 | <.0001 | 0.05 |
| TRTPN | LSMeans, IDeg | WORK.ADATA2 | 54.6559 | 0.6092 | 715 | 89.72 | <.0001 | 0.05 |
| TRTPN | LSMeans, Lira | WORK.ADATA2 | 55.0238 | 0.6068 | 715 | 90.67 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| TRTPN | LSMeans, IDegLira | 47.3145 | 48.9975 | 8.201E20 | 3.535E20 | 1.903E21 |
| TRTPN | LSMeans, IDeg | 53.4599 | 55.8519 | 5.454E23 | 1.649E23 | 1.804E24 |
| TRTPN | LSMeans, Lira | 53.8324 | 56.2152 | 7.88E23 | 2.394E23 | 2.594E24 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| TRTPN | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -6.4999 | 0.7453 | 715 | -8.72 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| TRTPN | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -7.9631 | -5.0367 | 0.001504 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| TRTPN | Treatment contrast, IDegLira - IDeg | 0.000348 | 0.006495 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| TRTPN | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -6.8678 | 0.7428 | 715 | -9.25 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| TRTPN | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -8.3262 | -5.4094 | 0.001041 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| TRTPN | Treatment contrast, IDegLira - Lira | 0.000242 | 0.004474 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.5548 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1635.3 |
| AIC (Smaller is Better) | 1637.3 |
| AICC (Smaller is Better) | 1637.3 |
| BIC (Smaller is Better) | 1641.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.5634 | 0.2879 | 715 | 15.85 | <.0001 | 0.05 |
| TRTPN | | 1 | -0.6283 | 0.06796 | 715 | -9.25 | <.0001 | 0.05 |
| TRTPN | | 2 | -0.03366 | 0.07869 | 715 | -0.43 | 0.6690 | 0.05 |
| TRTPN | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3922 | 0.05944 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.6662 | 0.03413 | 715 | -19.52 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 3.9982 | 5.1287 |
| TRTPN | | 1 | -0.7618 | -0.4949 |
| TRTPN | | 2 | -0.1882 | 0.1208 |
| TRTPN | | 3 | | |
| PREOAD2 | Metformin | | -0.5089 | -0.2755 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7332 | -0.5992 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| TRTPN | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 380.96 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| TRTPN | Change from baseline, IDegLira | WORK.ADATA2 | -1.6769 | 0.03921 | 715 | -42.76 | <.0001 |
| TRTPN | Change from baseline, IDeg | WORK.ADATA2 | -1.0822 | 0.05574 | 715 | -19.42 | <.0001 |
| TRTPN | Change from baseline, Lira | WORK.ADATA2 | -1.0485 | 0.05552 | 715 | -18.89 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| TRTPN | Change from baseline, IDegLira | 0.05 | -1.7539 | -1.5999 |
| TRTPN | Change from baseline, IDeg | 0.05 | -1.1916 | -0.9728 |
| TRTPN | Change from baseline, Lira | 0.05 | -1.1575 | -0.9395 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 66.2773 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5060.0 |
| AIC (Smaller is Better) | 5062.0 |
| AICC (Smaller is Better) | 5062.0 |
| BIC (Smaller is Better) | 5066.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 34.2233 | 2.3673 | 715 | 14.46 | <.0001 | 0.05 |
| TRTPN | | 1 | -6.8678 | 0.7428 | 715 | -9.25 | <.0001 | 0.05 |
| TRTPN | | 2 | -0.3679 | 0.8601 | 715 | -0.43 | 0.6690 | 0.05 |
| TRTPN | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.2869 | 0.6497 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.6662 | 0.03413 | 715 | -19.52 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 29.5757 | 38.8709 |
| TRTPN | | 1 | -8.3262 | -5.4094 |
| TRTPN | | 2 | -2.0566 | 1.3207 |
| TRTPN | | 3 | | |
| PREOAD2 | Metformin | | -5.5625 | -3.0113 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7332 | -0.5992 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| TRTPN | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 380.96 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| TRTPN | Change from baseline, IDegLira | WORK.ADATA2 | -18.3282 | 0.4286 | 715 | -42.76 | <.0001 |
| TRTPN | Change from baseline, IDeg | WORK.ADATA2 | -11.8284 | 0.6092 | 715 | -19.42 | <.0001 |
| TRTPN | Change from baseline, Lira | WORK.ADATA2 | -11.4604 | 0.6068 | 715 | -18.89 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| TRTPN | Change from baseline, IDegLira | 0.05 | -19.1697 | -17.4868 |
| TRTPN | Change from baseline, IDeg | 0.05 | -13.0244 | -10.6323 |
| TRTPN | Change from baseline, Lira | 0.05 | -12.6519 | -10.2690 |

3: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.4940 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1453.8 |
| AIC (Smaller is Better) | 1455.8 |
| AICC (Smaller is Better) | 1455.8 |
| BIC (Smaller is Better) | 1460.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.7125 | 0.2803 | 669 | 16.81 | <.0001 | 0.05 |
| trtan | | 1 | -0.5903 | 0.06726 | 669 | -8.78 | <.0001 | 0.05 |
| trtan | | 2 | -0.00164 | 0.07752 | 669 | -0.02 | 0.9832 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3963 | 0.05779 | 669 | -6.86 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.3060 | 0.03321 | 669 | 9.21 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|---------|---------|
| Intercept | | | 4.1621 | 5.2628 |
| trtan | | 1 | -0.7224 | -0.4583 |
| trtan | | 2 | -0.1538 | 0.1506 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | -0.5097 | -0.2828 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2408 | 0.3712 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 59.18 | <.0001 |
| PREOAD2 | 1 | 669 | 47.01 | <.0001 |
| BASE | 1 | 669 | 84.90 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtan | LSMeans, IDegLira | WORK.ADATA2 | 6.5112 | 0.03790 | 669 | 171.78 | <.0001 | 0.05 |
| trtan | LSMeans, IDeg | WORK.ADATA2 | 7.0999 | 0.05398 | 669 | 131.54 | <.0001 | 0.05 |
| trtan | LSMeans, Lira | WORK.ADATA2 | 7.1016 | 0.05558 | 669 | 127.78 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtan | LSMeans, IDegLira | 6.4368 | 6.5856 | 672.65 | 624.40 | 724.62 |
| trtan | LSMeans, IDeg | 6.9939 | 7.2059 | 1211.88 | 1090.02 | 1347.38 |
| trtan | LSMeans, Lira | 6.9924 | 7.2107 | 1213.87 | 1088.37 | 1353.83 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.5887 | 0.06599 | 669 | -8.92 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtan | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -0.7183 | -0.4591 | 0.5550 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - IDeg | 0.4876 | 0.6318 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C64849B

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -0.5903 | 0.06726 | 669 | -8.78 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtan | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -0.7224 | -0.4583 | 0.5541 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - Lira | 0.4856 | 0.6324 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 59.0097 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4658.5 |
| AIC (Smaller is Better) | 4660.5 |
| AICC (Smaller is Better) | 4660.5 |
| BIC (Smaller is Better) | 4665.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 35.1977 | 2.3063 | 669 | 15.26 | <.0001 | 0.05 |
| trtan | | 1 | -6.4525 | 0.7351 | 669 | -8.78 | <.0001 | 0.05 |
| trtan | | 2 | -0.01787 | 0.8472 | 669 | -0.02 | 0.9832 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.3311 | 0.6317 | 669 | -6.86 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.3060 | 0.03321 | 669 | 9.21 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|---------|---------|
| Intercept | | | 30.6693 | 39.7261 |
| trtan | | 1 | -7.8959 | -5.0090 |
| trtan | | 2 | -1.6814 | 1.6457 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | -5.5714 | -3.0908 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2408 | 0.3712 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 59.18 | <.0001 |
| PREOAD2 | 1 | 669 | 47.01 | <.0001 |
| BASE | 1 | 669 | 84.90 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtan | LSMeans, IDegLira | WORK.ADATA2 | 47.6677 | 0.4143 | 669 | 115.06 | <.0001 | 0.05 |
| trtan | LSMeans, IDeg | WORK.ADATA2 | 54.1023 | 0.5900 | 669 | 91.71 | <.0001 | 0.05 |
| trtan | LSMeans, Lira | WORK.ADATA2 | 54.1201 | 0.6075 | 669 | 89.09 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtan | LSMeans, IDegLira | 46.8542 | 48.4811 | 5.033E20 | 2.231E20 | 1.135E21 |
| trtan | LSMeans, IDeg | 52.9439 | 55.2606 | 3.136E23 | 9.845E22 | 9.986E23 |
| trtan | LSMeans, Lira | 52.9274 | 55.3129 | 3.192E23 | 9.684E22 | 1.052E24 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -6.4346 | 0.7213 | 669 | -8.92 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtan | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -7.8508 | -5.0183 | 0.001605 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - IDeg | 0.000389 | 0.006615 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -6.4525 | 0.7351 | 669 | -8.78 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtan | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -7.8959 | -5.0090 | 0.001577 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - Lira | 0.000372 | 0.006678 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.4940 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1453.8 |
| AIC (Smaller is Better) | 1455.8 |
| AICC (Smaller is Better) | 1455.8 |
| BIC (Smaller is Better) | 1460.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.7125 | 0.2803 | 669 | 16.81 | <.0001 | 0.05 |
| trtan | | 1 | -0.5903 | 0.06726 | 669 | -8.78 | <.0001 | 0.05 |
| trtan | | 2 | -0.00164 | 0.07752 | 669 | -0.02 | 0.9832 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3963 | 0.05779 | 669 | -6.86 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.6940 | 0.03321 | 669 | -20.90 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|---------|---------|
| Intercept | | | 4.1621 | 5.2628 |
| trtan | | 1 | -0.7224 | -0.4583 |
| trtan | | 2 | -0.1538 | 0.1506 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | -0.5097 | -0.2828 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7592 | -0.6288 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 59.18 | <.0001 |
| PREOAD2 | 1 | 669 | 47.01 | <.0001 |
| BASE | 1 | 669 | 436.75 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtan | Change from baseline, IDegLira | WORK.ADATA2 | -1.7233 | 0.03790 | 669 | -45.47 | <.0001 |
| trtan | Change from baseline, IDeg | WORK.ADATA2 | -1.1346 | 0.05398 | 669 | -21.02 | <.0001 |
| trtan | Change from baseline, Lira | WORK.ADATA2 | -1.1330 | 0.05558 | 669 | -20.39 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtan | Change from baseline, IDegLira | 0.05 | -1.7978 | -1.6489 |
| trtan | Change from baseline, IDeg | 0.05 | -1.2406 | -1.0287 |
| trtan | Change from baseline, Lira | 0.05 | -1.2421 | -1.0239 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 59.0097 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4658.5 |
| AIC (Smaller is Better) | 4660.5 |
| AICC (Smaller is Better) | 4660.5 |
| BIC (Smaller is Better) | 4665.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 35.1977 | 2.3063 | 669 | 15.26 | <.0001 | 0.05 |
| trtan | | 1 | -6.4525 | 0.7351 | 669 | -8.78 | <.0001 | 0.05 |
| trtan | | 2 | -0.01787 | 0.8472 | 669 | -0.02 | 0.9832 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.3311 | 0.6317 | 669 | -6.86 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.6940 | 0.03321 | 669 | -20.90 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|---------|---------|
| Intercept | | | 30.6693 | 39.7261 |
| trtan | | 1 | -7.8959 | -5.0090 |
| trtan | | 2 | -1.6814 | 1.6457 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | -5.5714 | -3.0908 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7592 | -0.6288 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 59.18 | <.0001 |
| PREOAD2 | 1 | 669 | 47.01 | <.0001 |
| BASE | 1 | 669 | 436.75 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtan | Change from baseline, IDegLira | WORK.ADATA2 | -18.8362 | 0.4143 | 669 | -45.47 | <.0001 |
| trtan | Change from baseline, IDeg | WORK.ADATA2 | -12.4016 | 0.5900 | 669 | -21.02 | <.0001 |
| trtan | Change from baseline, Lira | WORK.ADATA2 | -12.3837 | 0.6075 | 669 | -20.39 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| trtan | Change from baseline, IDegLira | 0.05 | -19.6496 | -18.0227 |
| trtan | Change from baseline, IDeg | 0.05 | -13.5600 | -11.2432 |
| trtan | Change from baseline, Lira | 0.05 | -13.5765 | -11.1910 |

4: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.4598 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1374.9 |
| AIC (Smaller is Better) | 1376.9 |
| AICC (Smaller is Better) | 1376.9 |
| BIC (Smaller is Better) | 1381.4 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.8534 | 0.2736 | 654 | 17.74 | <.0001 | 0.05 |
| trtpn | | 1 | -0.5474 | 0.06629 | 654 | -8.26 | <.0001 | 0.05 |
| trtpn | | 2 | 0.02449 | 0.07622 | 654 | 0.32 | 0.7481 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.4131 | 0.05637 | 654 | -7.33 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.2840 | 0.03241 | 654 | 8.77 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 4.3162 | 5.3906 |
| trtpn | | 1 | -0.6776 | -0.4173 |
| trtpn | | 2 | -0.1252 | 0.1742 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5238 | -0.3025 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2204 | 0.3477 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 56.18 | <.0001 |
| PREOAD2 | 1 | 654 | 53.71 | <.0001 |
| BASE | 1 | 654 | 76.83 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 6.5085 | 0.03673 | 654 | 177.21 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 7.0805 | 0.05252 | 654 | 134.81 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 7.0560 | 0.05520 | 654 | 127.83 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 6.4364 | 6.5807 | 670.84 | 624.16 | 721.01 |
| trtpn | LSMeans, IDeg | 6.9773 | 7.1836 | 1188.52 | 1072.06 | 1317.64 |
| trtpn | LSMeans, Lira | 6.9476 | 7.1644 | 1159.77 | 1040.64 | 1292.54 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.5719 | 0.06411 | 654 | -8.92 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -0.6978 | -0.4460 | 0.5644 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.4977 | 0.6402 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C64849B

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -0.5474 | 0.06629 | 654 | -8.26 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -0.6776 | -0.4173 | 0.5784 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.5078 | 0.6588 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 54.9347 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4507.8 |
| AIC (Smaller is Better) | 4509.8 |
| AICC (Smaller is Better) | 4509.8 |
| BIC (Smaller is Better) | 4514.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 36.2227 | 2.2522 | 654 | 16.08 | <.0001 | 0.05 |
| trtpn | | 1 | -5.9836 | 0.7246 | 654 | -8.26 | <.0001 | 0.05 |
| trtpn | | 2 | 0.2677 | 0.8331 | 654 | 0.32 | 0.7481 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.5157 | 0.6162 | 654 | -7.33 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.2840 | 0.03241 | 654 | 8.77 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 31.8002 | 40.6451 |
| trtpn | | 1 | -7.4064 | -4.5608 |
| trtpn | | 2 | -1.3682 | 1.9036 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -5.7256 | -3.3058 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2204 | 0.3477 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 56.18 | <.0001 |
| PREOAD2 | 1 | 654 | 53.71 | <.0001 |
| BASE | 1 | 654 | 76.83 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 47.6382 | 0.4014 | 654 | 118.67 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 53.8895 | 0.5741 | 654 | 93.87 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 53.6218 | 0.6033 | 654 | 88.88 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 46.8500 | 48.4265 | 4.887E20 | 2.222E20 | 1.075E21 |
| trtpn | LSMeans, IDeg | 52.7623 | 55.0167 | 2.535E23 | 8.211E22 | 7.825E23 |
| trtpn | LSMeans, Lira | 52.4372 | 54.8065 | 1.939E23 | 5.932E22 | 6.341E23 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -6.2513 | 0.7007 | 654 | -8.92 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -7.6272 | -4.8753 | 0.001928 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.000487 | 0.007633 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -5.9836 | 0.7246 | 654 | -8.26 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -7.4064 | -4.5608 | 0.002520 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.000607 | 0.01045 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.4598 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1374.9 |
| AIC (Smaller is Better) | 1376.9 |
| AICC (Smaller is Better) | 1376.9 |
| BIC (Smaller is Better) | 1381.4 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.8534 | 0.2736 | 654 | 17.74 | <.0001 | 0.05 |
| trtpn | | 1 | -0.5474 | 0.06629 | 654 | -8.26 | <.0001 | 0.05 |
| trtpn | | 2 | 0.02449 | 0.07622 | 654 | 0.32 | 0.7481 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.4131 | 0.05637 | 654 | -7.33 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.7160 | 0.03241 | 654 | -22.09 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 4.3162 | 5.3906 |
| trtpn | | 1 | -0.6776 | -0.4173 |
| trtpn | | 2 | -0.1252 | 0.1742 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5238 | -0.3025 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7796 | -0.6523 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 56.18 | <.0001 |
| PREOAD2 | 1 | 654 | 53.71 | <.0001 |
| BASE | 1 | 654 | 488.10 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -1.7247 | 0.03673 | 654 | -46.96 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -1.1528 | 0.05252 | 654 | -21.95 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -1.1773 | 0.05520 | 654 | -21.33 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -1.7968 | -1.6526 |
| trtpn | Change from baseline, IDeg | 0.05 | -1.2559 | -1.0496 |
| trtpn | Change from baseline, Lira | 0.05 | -1.2856 | -1.0689 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
 completer analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter
 Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 54.9347 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4507.8 |
| AIC (Smaller is Better) | 4509.8 |
| AICC (Smaller is Better) | 4509.8 |
| BIC (Smaller is Better) | 4514.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|--|---|----------|-------------------|-----|---------|---------|-------|
| Intercept | | | 36.2227 | 2.2522 | 654 | 16.08 | <.0001 | 0.05 |
| trtpn | | 1 | -5.9836 | 0.7246 | 654 | -8.26 | <.0001 | 0.05 |
| trtpn | | 2 | 0.2677 | 0.8331 | 654 | 0.32 | 0.7481 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.5157 | 0.6162 | 654 | -7.33 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.7160 | 0.03241 | 654 | -22.09 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 31.8002 | 40.6451 |
| trtpn | | 1 | -7.4064 | -4.5608 |
| trtpn | | 2 | -1.3682 | 1.9036 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -5.7256 | -3.3058 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7796 | -0.6523 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 56.18 | <.0001 |
| PREOAD2 | 1 | 654 | 53.71 | <.0001 |
| BASE | 1 | 654 | 488.10 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -18.8510 | 0.4014 | 654 | -46.96 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -12.5997 | 0.5741 | 654 | -21.95 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -12.8674 | 0.6033 | 654 | -21.33 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| trtpn | Change from baseline, IDegLira | 0.05 | -19.6393 | -18.0627 |
| trtpn | Change from baseline, IDeg | 0.05 | -13.7269 | -11.4725 |
| trtpn | Change from baseline, Lira | 0.05 | -14.0521 | -11.6827 |

**5: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set**

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | AVAL |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| AVISITN | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Class Level Information

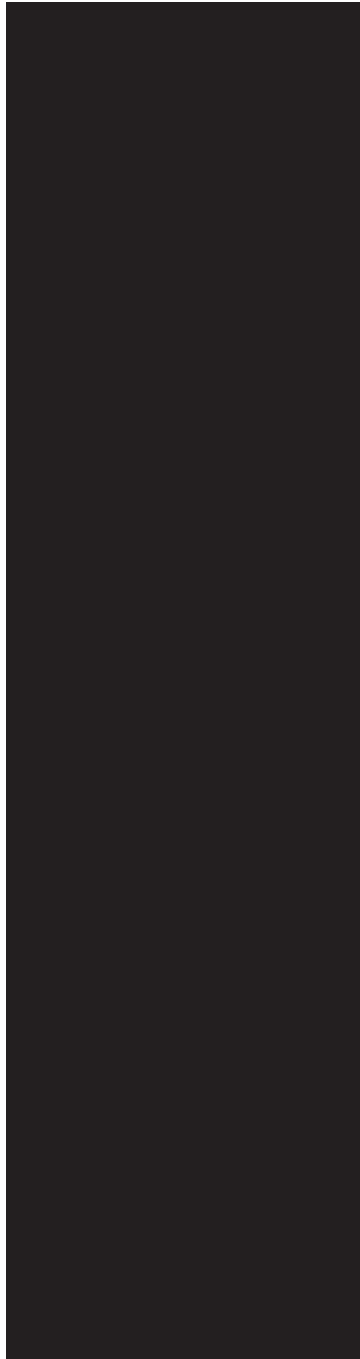
| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

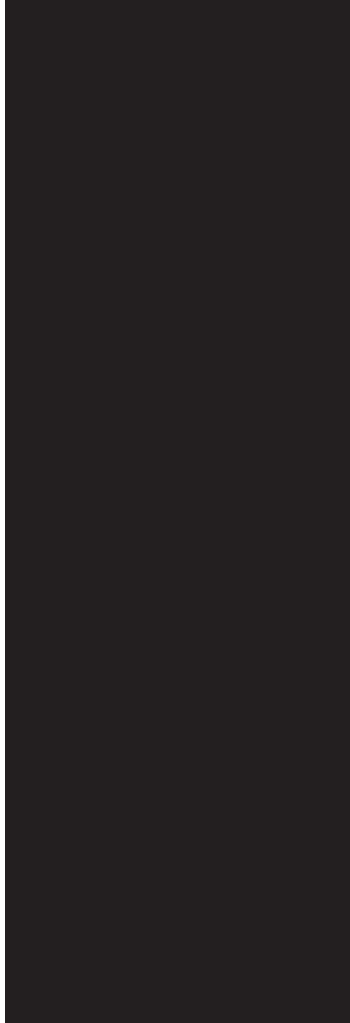
The Mixed Procedure



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4041 |
| Number of Observations Not Used | 279 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
 - full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 7781.56844929 | |
| 1 | 3 | 2512.22254080 | 0.00036020 |
| 2 | 1 | 2511.34737835 | 0.00000107 |
| 3 | 1 | 2511.34477278 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2511.3 |
| AIC (Smaller is Better) | 2553.3 |
| AICC (Smaller is Better) | 2553.6 |
| BIC (Smaller is Better) | 2649.5 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 5270.22 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-------------------|--------|--------|---------|--------|
| TRT01PN (AVISITN) | 12 | 828 | 18.08 | <.0001 |
| PREOAD2 (AVISITN) | 6 | 668 | 10.71 | <.0001 |
| BASE (AVISITN) | 6 | 670 | 308.22 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|-------------------|-------------------|---------------|----------|----------------|-------|---------|---------|
| TRT01PN (AVISITN) | LSMeans, IDegLira | WORK.ANA_DATA | 6.5097 | 0.03704 | 658.2 | 175.76 | <.0001 |
| TRT01PN (AVISITN) | LSMeans, IDeg | WORK.ANA_DATA | 7.1047 | 0.05281 | 660.9 | 134.54 | <.0001 |
| TRT01PN (AVISITN) | LSMeans, Lira | WORK.ANA_DATA | 7.1015 | 0.05446 | 683.2 | 130.40 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|-------------------|-------------------|-------|--------|--------|
| TRT01PN (AVISITN) | LSMeans, IDegLira | 0.05 | 6.4370 | 6.5825 |
| TRT01PN (AVISITN) | LSMeans, IDeg | 0.05 | 7.0011 | 7.2084 |
| TRT01PN (AVISITN) | LSMeans, Lira | 0.05 | 6.9946 | 7.2085 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | AVAL |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| AVISITN | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

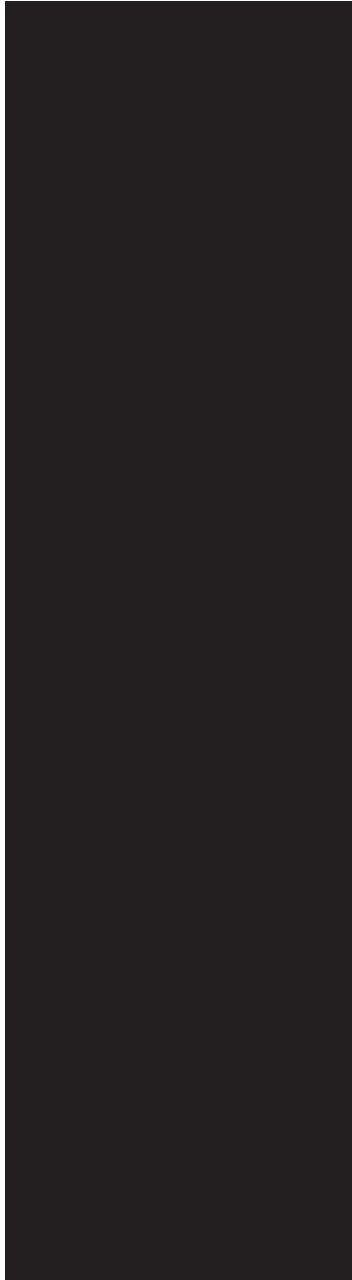
HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Class Level Information

| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

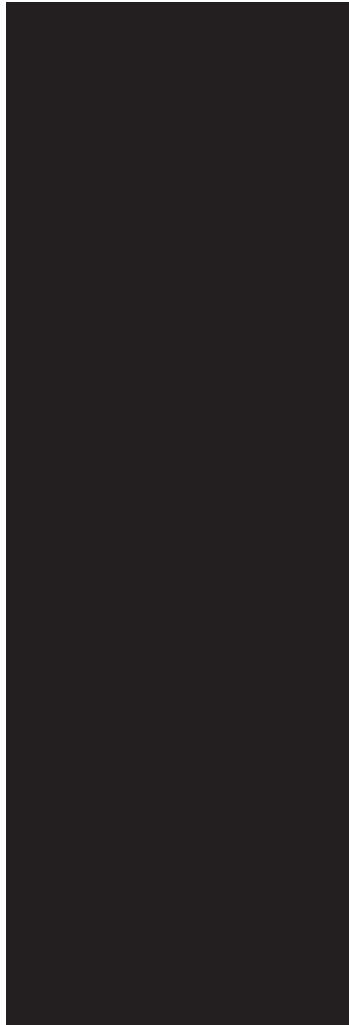
The Mixed Procedure



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4041 |
| Number of Observations Not Used | 279 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 26994.97025107 | |
| 1 | 3 | 21725.62434258 | 0.00012195 |
| 2 | 1 | 21724.74918014 | 0.00000036 |
| 3 | 1 | 21724.74657456 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|---------|
| -2 Res Log Likelihood | 21724.7 |
| AIC (Smaller is Better) | 21766.7 |
| AICC (Smaller is Better) | 21767.0 |
| BIC (Smaller is Better) | 21862.9 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 5270.22 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-------------------|--------|--------|---------|--------|
| TRT01PN (AVISITN) | 12 | 828 | 18.08 | <.0001 |
| PREOAD2 (AVISITN) | 6 | 668 | 10.71 | <.0001 |
| BASE (AVISITN) | 6 | 670 | 308.22 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|-------------------|-------------------|---------------|----------|----------------|-------|---------|---------|
| TRT01PN (AVISITN) | LSMeans, IDegLira | WORK.ANA_DATA | 47.6513 | 0.4048 | 658.2 | 117.71 | <.0001 |
| TRT01PN (AVISITN) | LSMeans, IDeg | WORK.ANA_DATA | 54.1549 | 0.5772 | 660.9 | 93.83 | <.0001 |
| TRT01PN (AVISITN) | LSMeans, Lira | WORK.ANA_DATA | 54.1197 | 0.5952 | 683.2 | 90.92 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|-------------------|-------------------|-------|---------|---------|
| TRT01PN (AVISITN) | LSMeans, IDegLira | 0.05 | 46.8564 | 48.4462 |
| TRT01PN (AVISITN) | LSMeans, IDeg | 0.05 | 53.0216 | 55.2882 |
| TRT01PN (AVISITN) | LSMeans, Lira | 0.05 | 52.9510 | 55.2884 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | CHG |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| AVISITN | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Class Level Information

| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4041 |
| Number of Observations Not Used | 279 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 7781.56844929 | |
| 1 | 3 | 2512.22254080 | 0.00036020 |
| 2 | 1 | 2511.34737835 | 0.00000107 |
| 3 | 1 | 2511.34477278 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2511.3 |
| AIC (Smaller is Better) | 2553.3 |
| AICC (Smaller is Better) | 2553.6 |
| BIC (Smaller is Better) | 2649.5 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 5270.22 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-------------------|--------|--------|---------|--------|
| TRT01PN (AVISITN) | 12 | 828 | 18.08 | <.0001 |
| PREOAD2 (AVISITN) | 6 | 668 | 10.71 | <.0001 |
| BASE (AVISITN) | 6 | 670 | 83.04 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
 - full analysis set

Short Topic Code=C64849B Long label=HbA1c (%)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|-------------------|--------------------------------|---------------|----------|----------------|-------|---------|
| TRT01PN (AVISITN) | Change from baseline, IDegLira | WORK.ANA_DATA | -1.7275 | 0.03704 | 658.2 | -46.64 |
| TRT01PN (AVISITN) | Change from baseline, IDeg | WORK.ANA_DATA | -1.1325 | 0.05281 | 660.9 | -21.45 |
| TRT01PN (AVISITN) | Change from baseline, Lira | WORK.ANA_DATA | -1.1357 | 0.05446 | 683.2 | -20.85 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper |
|-------------------|--------------------------------|---------|-------|---------|---------|
| TRT01PN (AVISITN) | Change from baseline, IDegLira | <.0001 | 0.05 | -1.8002 | -1.6548 |
| TRT01PN (AVISITN) | Change from baseline, IDeg | <.0001 | 0.05 | -1.2362 | -1.0288 |
| TRT01PN (AVISITN) | Change from baseline, Lira | <.0001 | 0.05 | -1.2426 | -1.0288 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF |
|-------------------|-------------------------------------|---------------|----------|----------------|-------|
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - IDeg | WORK.ANA_DATA | -0.5950 | 0.06453 | 659.9 |
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - Lira | WORK.ANA_DATA | -0.5918 | 0.06585 | 675.3 |

Least Squares Means Estimates

| Effect | Label | t Value | Pr > t | Alpha | Lower | Upper |
|-------------------|-------------------------------------|---------|---------|-------|---------|---------|
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - IDeg | -9.22 | <.0001 | 0.05 | -0.7217 | -0.4683 |
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - Lira | -8.99 | <.0001 | 0.05 | -0.7211 | -0.4625 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | CHG |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| AVISITN | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Class Level Information

| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure



HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4041 |
| Number of Observations Not Used | 279 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 26994.97025107 | |
| 1 | 3 | 21725.62434258 | 0.00012195 |
| 2 | 1 | 21724.74918014 | 0.00000036 |
| 3 | 1 | 21724.74657456 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|---------|
| -2 Res Log Likelihood | 21724.7 |
| AIC (Smaller is Better) | 21766.7 |
| AICC (Smaller is Better) | 21767.0 |
| BIC (Smaller is Better) | 21862.9 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 5270.22 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-------------------|--------|--------|---------|--------|
| TRT01PN (AVISITN) | 12 | 828 | 18.08 | <.0001 |
| PREOAD2 (AVISITN) | 6 | 668 | 10.71 | <.0001 |
| BASE (AVISITN) | 6 | 670 | 83.04 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
 - full analysis set

Short Topic Code=HBA1CONV Long label=HbA1c (mmol/mol)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|-------------------|--------------------------------|---------------|----------|----------------|-------|---------|
| TRT01PN (AVISITN) | Change from baseline, IDegLira | WORK.ANA_DATA | -18.8815 | 0.4048 | 658.2 | -46.64 |
| TRT01PN (AVISITN) | Change from baseline, IDeg | WORK.ANA_DATA | -12.3779 | 0.5772 | 660.9 | -21.45 |
| TRT01PN (AVISITN) | Change from baseline, Lira | WORK.ANA_DATA | -12.4131 | 0.5952 | 683.2 | -20.85 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper |
|-------------------|--------------------------------|---------|-------|----------|----------|
| TRT01PN (AVISITN) | Change from baseline, IDegLira | <.0001 | 0.05 | -19.6764 | -18.0866 |
| TRT01PN (AVISITN) | Change from baseline, IDeg | <.0001 | 0.05 | -13.5112 | -11.2446 |
| TRT01PN (AVISITN) | Change from baseline, Lira | <.0001 | 0.05 | -13.5818 | -11.2444 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF |
|-------------------|-------------------------------------|---------------|----------|----------------|-------|
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - IDeg | WORK.ANA_DATA | -6.5036 | 0.7053 | 659.9 |
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - Lira | WORK.ANA_DATA | -6.4683 | 0.7197 | 675.3 |

Least Squares Means Estimates

| Effect | Label | t Value | Pr > t | Alpha | Lower | Upper |
|-------------------|-------------------------------------|---------|---------|-------|---------|---------|
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - IDeg | -9.22 | <.0001 | 0.05 | -7.8885 | -5.1186 |
| TRT01PN (AVISITN) | Treatment contrast, IDegLira - Lira | -8.99 | <.0001 | 0.05 | -7.8815 | -5.0552 |

6: HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=12 Parameter Code=C64849B Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000195 | 0.002826 | 0.003022 | 238192 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.069246 | 0.064770 | 0.999935 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 7.103584 | 0.054969 | 6.995846 | 7.211322 | 238192 | 7.062800 | 7.156116 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 129.23 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=12 Parameter Code=C64849B Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000084942 | 0.001399 | 0.001484 | 304281 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.060781 | 0.057305 | 0.999943 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 6.548286 | 0.038522 | 6.472785 | 6.623788 | 304281 | 6.518629 | 6.575295 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 169.99 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=12 Parameter Code=C64849B Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|-------------------|
| Data Set | WORK.LSME_ABS_MI2 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.000425 | 0.002804 | 0.003230 | 57506 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.151813 | 0.131833 | 0.999868 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|-------|----------|----------|
| Estimate | 7.107344 | 0.056832 | 6.995953 | 7.218735 | 57506 | 7.045183 | 7.178137 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 125.06 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=22 Parameter Code=HBA1CONV Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.023354 | 0.337598 | 0.360976 | 238192 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.069246 | 0.064770 | 0.999935 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 54.142174 | 0.600812 | 52.96460 | 55.31975 | 238192 | 53.696405 | 54.716345 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 90.11 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=22 Parameter Code=HBA1CONV Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.010148 | 0.167118 | 0.177276 | 304281 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.060781 | 0.057305 | 0.999943 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 48.072770 | 0.421042 | 47.24754 | 48.89800 | 304281 | 47.748618 | 48.367977 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 114.18 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=22 Parameter Code=HBA1CONV Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.050806 | 0.334999 | 0.385856 | 57506 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.151813 | 0.131833 | 0.999868 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | 54.183273 | 0.621173 | 52.96577 | 55.40078 | 57506 | 53.503846 | 54.957040 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 87.23 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=12 Parameter Code=C64849B Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000195 | 0.002826 | 0.003022 | 238192 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.069246 | 0.064770 | 0.999935 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -1.129194 | 0.054969 | -1.23693 | -1.02146 | 238192 | -1.169978 | -1.076662 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -20.54 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=12 Parameter Code=C64849B Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000084942 | 0.001399 | 0.001484 | 304281 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.060781 | 0.057305 | 0.999943 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -1.684491 | 0.038522 | -1.75999 | -1.60899 | 304281 | -1.714149 | -1.657483 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -43.73 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=12 Parameter Code=C64849B Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.000425 | 0.002804 | 0.003230 | 57506 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.151813 | 0.131833 | 0.999868 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -1.125433 | 0.056832 | -1.23682 | -1.01404 | 57506 | -1.187595 | -1.054641 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -19.80 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=12 Parameter Code=C64849B Label=Treatment contrast, IDegLira - IDeg

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000265 | 0.004230 | 0.004495 | 286688 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.062734 | 0.059037 | 0.999941 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -0.555298 | 0.067045 | -0.68670 | -0.42389 | 286688 | -0.609658 | -0.503912 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -8.28 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=22 Parameter Code=HBA1CONV Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.023354 | 0.337598 | 0.360976 | 238192 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.069246 | 0.064770 | 0.999935 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | -12.342087 | 0.600812 | -13.5197 | -11.1645 | 238192 | -12.787856 | -11.767916 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -20.54 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=22 Parameter Code=HBA1CONV Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.010148 | 0.167118 | 0.177276 | 304281 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.060781 | 0.057305 | 0.999943 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | -18.411491 | 0.421042 | -19.2367 | -17.5863 | 304281 | -18.735643 | -18.116284 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -43.73 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=22 Parameter Code=HBA1CONV Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.050806 | 0.334999 | 0.385856 | 57506 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.151813 | 0.131833 | 0.999868 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|-------|------------|------------|
| Estimate | -12.300988 | 0.621173 | -13.5185 | -11.0835 | 57506 | -12.980415 | -11.527221 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -19.80 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=22 Parameter Code=HBA1CONV Label=Treatment contrast, IDegLira - IDeg

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.031667 | 0.505294 | 0.536993 | 286688 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.062734 | 0.059037 | 0.999941 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -6.069404 | 0.732798 | -7.50567 | -4.63314 | 286688 | -6.663557 | -5.507762 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -8.28 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=13 Parameter Code=C64849B Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000194 | 0.002751 | 0.002945 | 229712 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.070602 | 0.065955 | 0.999934 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 7.103029 | 0.054266 | 6.996669 | 7.209389 | 229712 | 7.062298 | 7.155185 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 130.89 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=13 Parameter Code=C64849B Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000072517 | 0.001362 | 0.001434 | 389972 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.053312 | 0.050618 | 0.999949 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 6.532857 | 0.037871 | 6.458631 | 6.607083 | 389972 | 6.505273 | 6.557992 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 172.50 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=13 Parameter Code=C64849B Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|-------------------|
| Data Set | WORK.LSME_ABS_MI3 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.000425 | 0.002729 | 0.003155 | 54889 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.155948 | 0.134940 | 0.999865 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|-------|----------|----------|
| Estimate | 7.107487 | 0.056170 | 6.997393 | 7.217581 | 54889 | 7.045149 | 7.178158 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 126.54 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=23 Parameter Code=HBA1CONV Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.023177 | 0.328601 | 0.351801 | 229712 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.070602 | 0.065955 | 0.999934 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 54.136108 | 0.593128 | 52.97359 | 55.29862 | 229712 | 53.690920 | 54.706169 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 91.27 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=23 Parameter Code=HBA1CONV Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.008663 | 0.162664 | 0.171336 | 389972 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.053312 | 0.050618 | 0.999949 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 47.904126 | 0.413928 | 47.09284 | 48.71541 | 389972 | 47.602638 | 48.178854 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 115.73 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=23 Parameter Code=HBA1CONV Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.050799 | 0.326071 | 0.376921 | 54889 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.155948 | 0.134940 | 0.999865 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | 54.184834 | 0.613939 | 52.98151 | 55.38816 | 54889 | 53.503476 | 54.957268 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 88.26 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=13 Parameter Code=C64849B Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000194 | 0.002751 | 0.002945 | 229712 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.070602 | 0.065955 | 0.999934 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -1.129749 | 0.054266 | -1.23611 | -1.02339 | 229712 | -1.170480 | -1.077593 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | -20.82 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=13 Parameter Code=C64849B Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000072517 | 0.001362 | 0.001434 | 389972 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.053312 | 0.050618 | 0.999949 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -1.699921 | 0.037871 | -1.77415 | -1.62570 | 389972 | -1.727504 | -1.674786 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -44.89 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=13 Parameter Code=C64849B Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|-------------------|
| Data Set | WORK.LSME_CHG_MI3 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.000425 | 0.002729 | 0.003155 | 54889 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.155948 | 0.134940 | 0.999865 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -1.125291 | 0.056170 | -1.23538 | -1.01520 | 54889 | -1.187629 | -1.054620 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | -20.03 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=13 Parameter Code=C64849B Label=Treatment contrast, IDegLira - Lira

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.000498 | 0.004090 | 0.004588 | 84745 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.121798 | 0.108595 | 0.999891 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -0.574630 | 0.067735 | -0.70739 | -0.44187 | 84745 | -0.643691 | -0.509073 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | -8.48 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=23 Parameter Code=HBA1CONV Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.023177 | 0.328601 | 0.351801 | 229712 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.070602 | 0.065955 | 0.999934 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | -12.348153 | 0.593128 | -13.5107 | -11.1856 | 229712 | -12.793341 | -11.778092 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -20.82 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=23 Parameter Code=HBA1CONV Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.008663 | 0.162664 | 0.171336 | 389972 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.053312 | 0.050618 | 0.999949 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | -18.580135 | 0.413928 | -19.3914 | -17.7688 | 389972 | -18.881623 | -18.305407 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -44.89 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=23 Parameter Code=HBA1CONV Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.050799 | 0.326071 | 0.376921 | 54889 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.155948 | 0.134940 | 0.999865 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|-------|------------|------------|
| Estimate | -12.299427 | 0.613939 | -13.5028 | -11.0961 | 54889 | -12.980785 | -11.526993 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -20.03 | <.0001 |

HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

PARAM_ANA_SORT=23 Parameter Code=HBA1CONV Label=Treatment contrast, IDegLira - Lira

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.059450 | 0.488595 | 0.548105 | 84745 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.121798 | 0.108595 | 0.999891 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -6.280708 | 0.740341 | -7.73177 | -4.82965 | 84745 | -7.035540 | -5.564170 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -8.48 | <.0001 |

7: HbA1c after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.5548 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1635.3 |
| AIC (Smaller is Better) | 1637.3 |
| AICC (Smaller is Better) | 1637.3 |
| BIC (Smaller is Better) | 1641.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.5634 | 0.2879 | 715 | 15.85 | <.0001 | 0.05 |
| trtpn | | 1 | -0.6283 | 0.06796 | 715 | -9.25 | <.0001 | 0.05 |
| trtpn | | 2 | -0.03366 | 0.07869 | 715 | -0.43 | 0.6690 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3922 | 0.05944 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.3338 | 0.03413 | 715 | 9.78 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 3.9982 | 5.1287 |
| trtpn | | 1 | -0.7618 | -0.4949 |
| trtpn | | 2 | -0.1882 | 0.1208 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5089 | -0.2755 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2668 | 0.4008 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 95.66 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 6.5559 | 0.03921 | 715 | 167.18 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 7.1506 | 0.05574 | 715 | 128.29 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 7.1842 | 0.05552 | 715 | 129.40 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 6.4789 | 6.6329 | 703.38 | 651.26 | 759.68 |
| trtpn | LSMeans, IDeg | 7.0412 | 7.2600 | 1274.85 | 1142.71 | 1422.27 |
| trtpn | LSMeans, Lira | 7.0752 | 7.2933 | 1318.50 | 1182.33 | 1470.34 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.5947 | 0.06819 | 715 | -8.72 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -0.7286 | -0.4608 | 0.5517 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.4826 | 0.6308 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -0.6283 | 0.06796 | 715 | -9.25 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -0.7618 | -0.4949 | 0.5335 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.4668 | 0.6096 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 66.2773 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5060.0 |
| AIC (Smaller is Better) | 5062.0 |
| AICC (Smaller is Better) | 5062.0 |
| BIC (Smaller is Better) | 5066.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 34.2233 | 2.3673 | 715 | 14.46 | <.0001 | 0.05 |
| trtpn | | 1 | -6.8678 | 0.7428 | 715 | -9.25 | <.0001 | 0.05 |
| trtpn | | 2 | -0.3679 | 0.8601 | 715 | -0.43 | 0.6690 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.2869 | 0.6497 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.3338 | 0.03413 | 715 | 9.78 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 29.5757 | 38.8709 |
| trtpn | | 1 | -8.3262 | -5.4094 |
| trtpn | | 2 | -2.0566 | 1.3207 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -5.5625 | -3.0113 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.2668 | 0.4008 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 95.66 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 48.1560 | 0.4286 | 715 | 112.35 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 54.6559 | 0.6092 | 715 | 89.72 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 55.0238 | 0.6068 | 715 | 90.67 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 47.3145 | 48.9975 | 8.201E20 | 3.535E20 | 1.903E21 |
| trtpn | LSMeans, IDeg | 53.4599 | 55.8519 | 5.454E23 | 1.649E23 | 1.804E24 |
| trtpn | LSMeans, Lira | 53.8324 | 56.2152 | 7.88E23 | 2.394E23 | 2.594E24 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -6.4999 | 0.7453 | 715 | -8.72 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -7.9631 | -5.0367 | 0.001504 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.000348 | 0.006495 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -6.8678 | 0.7428 | 715 | -9.25 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -8.3262 | -5.4094 | 0.001041 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.000242 | 0.004474 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.5548 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1635.3 |
| AIC (Smaller is Better) | 1637.3 |
| AICC (Smaller is Better) | 1637.3 |
| BIC (Smaller is Better) | 1641.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.5634 | 0.2879 | 715 | 15.85 | <.0001 | 0.05 |
| trtpn | | 1 | -0.6283 | 0.06796 | 715 | -9.25 | <.0001 | 0.05 |
| trtpn | | 2 | -0.03366 | 0.07869 | 715 | -0.43 | 0.6690 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3922 | 0.05944 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.6662 | 0.03413 | 715 | -19.52 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 3.9982 | 5.1287 |
| trtpn | | 1 | -0.7618 | -0.4949 |
| trtpn | | 2 | -0.1882 | 0.1208 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5089 | -0.2755 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7332 | -0.5992 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 380.96 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -1.6769 | 0.03921 | 715 | -42.76 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -1.0822 | 0.05574 | 715 | -19.42 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -1.0485 | 0.05552 | 715 | -18.89 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -1.7539 | -1.5999 |
| trtpn | Change from baseline, IDeg | 0.05 | -1.1916 | -0.9728 |
| trtpn | Change from baseline, Lira | 0.05 | -1.1575 | -0.9395 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 66.2773 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5060.0 |
| AIC (Smaller is Better) | 5062.0 |
| AICC (Smaller is Better) | 5062.0 |
| BIC (Smaller is Better) | 5066.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 34.2233 | 2.3673 | 715 | 14.46 | <.0001 | 0.05 |
| trtpn | | 1 | -6.8678 | 0.7428 | 715 | -9.25 | <.0001 | 0.05 |
| trtpn | | 2 | -0.3679 | 0.8601 | 715 | -0.43 | 0.6690 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.2869 | 0.6497 | 715 | -6.60 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.6662 | 0.03413 | 715 | -19.52 | <.0001 | 0.05 |

HbA1c after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 29.5757 | 38.8709 |
| trtpn | | 1 | -8.3262 | -5.4094 |
| trtpn | | 2 | -2.0566 | 1.3207 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -5.5625 | -3.0113 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.7332 | -0.5992 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 60.69 | <.0001 |
| PREOAD2 | 1 | 715 | 43.53 | <.0001 |
| BASE | 1 | 715 | 380.96 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -18.3282 | 0.4286 | 715 | -42.76 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -11.8284 | 0.6092 | 715 | -19.42 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -11.4604 | 0.6068 | 715 | -18.89 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| trtpn | Change from baseline, IDegLira | 0.05 | -19.1697 | -17.4868 |
| trtpn | Change from baseline, IDeg | 0.05 | -13.0244 | -10.6323 |
| trtpn | Change from baseline, Lira | 0.05 | -12.6519 | -10.2690 |

8: Responder for HbA1c treatment target - supportive statistical analysis - full analysis set

Parameter Code=HBA_BL65

The GENMOD Procedure

Model Information

Data Set WORK.ADATA2
 Distribution Binomial
 Link Function Logit
 Dependent Variable AVALC Analysis Value (C)

Number of Observations Read 720
 Number of Observations Used 720
 Number of Events 298
 Number of Trials 720

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 298 |
| 2 | N | 422 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBA1CBL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -412.3951 | |
| Full Log Likelihood | | -412.3951 | |
| AIC (smaller is better) | | 834.7901 | |
| AICC (smaller is better) | | 834.8741 | |
| BIC (smaller is better) | | 857.6864 | |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-----------|----|----------|----------------|----------------------------|-----------------|------------|
| Intercept | 1 | 3.3360 | 0.8860 | 1.5994 5.0726 | 14.18 | 0.0002 |
| trtpn 1 | 1 | 1.5276 | 0.2163 | 1.1037 1.9514 | 49.90 | <.0001 |
| trtpn 2 | 1 | 0.1533 | 0.2546 | -0.3456 0.6522 | 0.36 | 0.5469 |

Responder for HbA1c treatment target - supportive statistical analysis - full analysis set

Parameter Code=HBA_BL65

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|----------------------------|-----------------|------------|
| trtpn 3 | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| PREOAD2 Metformin | 1 | 1.1477 | 0.1809 | 0.7933 1.5022 | 40.27 | <.0001 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| HBA1CBL | 1 | -0.6000 | 0.1074 | -0.8105 -0.3894 | 31.19 | <.0001 |
| Scale | 0 | 1.0000 | 0.0000 | 1.0000 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | 0.4980 | 0.1204 | 4.14 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, IDeg | -0.8762 | 0.1800 | -4.87 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, Lira | -1.0295 | 0.1821 | -5.65 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | 0.2621 | 0.7340 | 1.6455 | 1.2997 | 2.0833 |
| trtpn | LSMeans frequency, IDeg | -1.2289 | -0.5235 | 0.4164 | 0.2926 | 0.5925 |
| trtpn | LSMeans frequency, Lira | -1.3864 | -0.6727 | 0.3572 | 0.2500 | 0.5103 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.3742 | 0.2140 | 6.42 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.5276 | 0.2163 | 7.06 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|--------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.9549 | 1.7936 | 3.9521 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.1037 | 1.9514 | 4.6070 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 2.5984 | 6.0111 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 3.0154 | 7.0387 |

Responder for HbA1c treatment target - supportive statistical analysis - full analysis set

Parameter Code=HBA_BL7

The GENMOD Procedure

Model Information

Data Set WORK.ADATA2
 Distribution Binomial
 Link Function Logit
 Dependent Variable AVALC Analysis Value (C)

Number of Observations Read 720
 Number of Observations Used 720
 Number of Events 448
 Number of Trials 720

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 448 |
| 2 | N | 272 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBALCBL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -402.2667 | |
| Full Log Likelihood | | -402.2667 | |
| AIC (smaller is better) | | 814.5335 | |
| AICC (smaller is better) | | 814.6175 | |
| BIC (smaller is better) | | 837.4297 | |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald | 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-----------|----|----------|----------------|---------|-----------------------|-----------------|------------|
| Intercept | 1 | 5.2013 | 0.9001 | 3.4371 | 6.9654 | 33.39 | <.0001 |
| trtpn 1 | 1 | 1.4327 | 0.2089 | 1.0234 | 1.8420 | 47.06 | <.0001 |
| trtpn 2 | 1 | -0.0143 | 0.2262 | -0.4576 | 0.4291 | 0.00 | 0.9497 |

Responder for HbA1c treatment target - supportive statistical analysis - full analysis set

Parameter Code=HBA_BL7

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|----------------------------|-----------------|------------|
| trtpn 3 | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| PREOAD2 Metformin | 1 | 1.1167 | 0.1969 | 0.7307 1.5026 | 32.16 | <.0001 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| HBA1CBL | 1 | -0.6859 | 0.1082 | -0.8979 -0.4739 | 40.22 | <.0001 |
| Scale | 0 | 1.0000 | 0.0000 | 1.0000 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | 1.5454 | 0.1465 | 10.55 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, IDeg | 0.09841 | 0.1657 | 0.59 | 0.5526 | 0.05 |
| trtpn | LSMeans frequency, Lira | 0.1127 | 0.1628 | 0.69 | 0.4889 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | 1.2582 | 1.8325 | 4.6897 | 3.5191 | 6.2497 |
| trtpn | LSMeans frequency, IDeg | -0.2264 | 0.4232 | 1.1034 | 0.7974 | 1.5268 |
| trtpn | LSMeans frequency, Lira | -0.2064 | 0.4317 | 1.1193 | 0.8135 | 1.5399 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.4470 | 0.2100 | 6.89 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.4327 | 0.2089 | 6.86 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|--------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.0354 | 1.8585 | 4.2502 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.0234 | 1.8420 | 4.1900 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 2.8163 | 6.4142 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 2.7825 | 6.3095 |

9: Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes - supportive statistical analysis - full analysis set

Parameter Code=HB65CHY

The GENMOD Procedure

Model Information

Data Set WORK.ADATA2
 Distribution Binomial
 Link Function Logit
 Dependent Variable AVALC Analysis Value (C)

Number of Observations Read 720
 Number of Observations Used 720
 Number of Events 284
 Number of Trials 720

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 284 |
| 2 | N | 436 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBA1CBL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -415.4484 | |
| Full Log Likelihood | | -415.4484 | |
| AIC (smaller is better) | | 840.8968 | |
| AICC (smaller is better) | | 840.9808 | |
| BIC (smaller is better) | | 863.7930 | |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-----------|----|----------|----------------|----------------------------|-----------------|------------|
| Intercept | 1 | 2.7202 | 0.8796 | 0.9962 4.4441 | 9.56 | 0.0020 |
| trtpn 1 | 1 | 1.4477 | 0.2161 | 1.0242 1.8712 | 44.90 | <.0001 |

Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes - supportive statistical analysis - full analysis set

Parameter Code=HB65CHY

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald | 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq | |
|-----------|-----------------|----------|----------------|---------|-----------------------|-----------------|------------|--------|
| trtpn | 2 | 0.1498 | 0.2562 | -0.3523 | 0.6519 | 0.34 | 0.5587 | |
| trtpn | 3 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | | |
| PREOAD2 | Metformin | 1 | 1.0974 | 0.1785 | 0.7475 | 1.4473 | <.0001 | |
| PREOAD2 | Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 | | | |
| HBA1CBL | | 1 | -0.5290 | 0.1063 | -0.7374 | -0.3207 | 24.77 | <.0001 |
| Scale | | 0 | 1.0000 | 0.0000 | 1.0000 | 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | 0.3613 | 0.1179 | 3.06 | 0.0022 | 0.05 |
| trtpn | LSMeans frequency, IDeg | -0.9366 | 0.1807 | -5.18 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, Lira | -1.0864 | 0.1834 | -5.92 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | 0.1302 | 0.5923 | 1.4352 | 1.1390 | 1.8082 |
| trtpn | LSMeans frequency, IDeg | -1.2908 | -0.5825 | 0.3920 | 0.2751 | 0.5585 |
| trtpn | LSMeans frequency, Lira | -1.4458 | -0.7270 | 0.3374 | 0.2356 | 0.4833 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.2979 | 0.2134 | 6.08 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.4477 | 0.2161 | 6.70 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|--------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.8796 | 1.7162 | 3.6616 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.0242 | 1.8712 | 4.2533 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 2.4099 | 5.5632 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 2.7849 | 6.4958 |

Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes - supportive statistical analysis - full analysis set

Parameter Code=HB7CHY

The GENMOD Procedure

Model Information

| | |
|--------------------|--------------------------|
| Data Set | WORK.ADATA2 |
| Distribution | Binomial |
| Link Function | Logit |
| Dependent Variable | AVALC Analysis Value (C) |

| | |
|-----------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Events | 429 |
| Number of Trials | 720 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 429 |
| 2 | N | 291 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBA1CBL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -422.3970 | |
| Full Log Likelihood | | -422.3970 | |
| AIC (smaller is better) | | 854.7939 | |
| AICC (smaller is better) | | 854.8780 | |
| BIC (smaller is better) | | 877.6902 | |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-----------|----|----------|----------------|----------------------------|-----------------|------------|
| Intercept | 1 | 4.1765 | 0.8669 | 2.4773 5.8757 | 23.21 | <.0001 |
| trtpn 1 | 1 | 1.2638 | 0.2022 | 0.8675 1.6600 | 39.08 | <.0001 |

Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes - supportive statistical analysis - full analysis set

Parameter Code=HB7CHY

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald | 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-----------|-----------------|----------|----------------|---------|-----------------------|-----------------|------------|
| trtpn | 2 | -0.0256 | 0.2239 | -0.4644 | 0.4133 | 0.01 | 0.9091 |
| trtpn | 3 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| PREOAD2 | Metformin | 1 | 1.0552 | 0.1883 | 0.6862 | 31.40 | <.0001 |
| PREOAD2 | Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 | | |
| HBA1CBL | | 1 | -0.5676 | 0.1040 | -0.7714 | 29.80 | <.0001 |
| Scale | | 0 | 1.0000 | 0.0000 | 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | 1.2949 | 0.1364 | 9.49 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, IDeg | 0.005601 | 0.1631 | 0.03 | 0.9726 | 0.05 |
| trtpn | LSMeans frequency, Lira | 0.03115 | 0.1606 | 0.19 | 0.8462 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | 1.0275 | 1.5623 | 3.6507 | 2.7941 | 4.7700 |
| trtpn | LSMeans frequency, IDeg | -0.3142 | 0.3254 | 1.0056 | 0.7304 | 1.3845 |
| trtpn | LSMeans frequency, Lira | -0.2836 | 0.3459 | 1.0316 | 0.7530 | 1.4133 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.2893 | 0.2034 | 6.34 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.2638 | 0.2022 | 6.25 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|--------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.8906 | 1.6881 | 3.6303 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 0.8675 | 1.6600 | 3.5387 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 2.4365 | 5.4090 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 2.3810 | 5.2593 |

10: Responder for HbA1c treatment target without weight gain - supportive statistical analysis - full analysis set

Parameter Code=HB65WOWG

The GENMOD Procedure

Model Information

| | |
|--------------------|--------------------------|
| Data Set | WORK.ADATA2 |
| Distribution | Binomial |
| Link Function | Logit |
| Dependent Variable | AVALC Analysis Value (C) |

| | |
|-----------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Events | 169 |
| Number of Trials | 720 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 169 |
| 2 | N | 551 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBALCBL | | |
| Prm8 | WGTBL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -365.5852 | |
| Full Log Likelihood | | -365.5852 | |
| AIC (smaller is better) | | 743.1705 | |
| AICC (smaller is better) | | 743.2883 | |
| BIC (smaller is better) | | 770.6460 | |

Algorithm converged.

Responder for HbA1c treatment target without weight gain - supportive statistical analysis - full analysis set

Parameter Code=HB65WOWG

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|----------------------------|---------|-----------------|------------|
| Intercept | 1 | 1.8407 | 1.1171 | -0.3489 | 4.0302 | 2.71 | 0.0994 |
| trtpn 1 | 1 | 0.5428 | 0.2209 | 0.1097 | 0.9758 | 6.04 | 0.0140 |
| trtpn 2 | 1 | -0.6440 | 0.3007 | -1.2334 | -0.0546 | 4.59 | 0.0322 |
| trtpn 3 | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| PREOAD2 Metformin | 1 | 0.4953 | 0.1891 | 0.1247 | 0.8660 | 6.86 | 0.0088 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| HBA1CBL | 1 | -0.4657 | 0.1184 | -0.6978 | -0.2336 | 15.46 | <.0001 |
| WGTL | 1 | 0.0056 | 0.0066 | -0.0072 | 0.0185 | 0.73 | 0.3923 |
| Scale | 0 | 1.0000 | 0.0000 | 1.0000 | 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | -0.7874 | 0.1214 | -6.48 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, IDeg | -1.9742 | 0.2366 | -8.34 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, Lira | -1.3302 | 0.1898 | -7.01 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | -1.0254 | -0.5494 | 0.4550 | 0.3586 | 0.5773 |
| trtpn | LSMeans frequency, IDeg | -2.4380 | -1.5104 | 0.1389 | 0.08734 | 0.2208 |
| trtpn | LSMeans frequency, Lira | -1.7021 | -0.9582 | 0.2644 | 0.1823 | 0.3836 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.1867 | 0.2630 | 4.51 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 0.5428 | 0.2209 | 2.46 | 0.0140 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|--------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.6713 | 1.7021 | 3.2764 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 0.1097 | 0.9758 | 1.7207 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.9569 | 5.4856 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.1160 | 2.6532 |

Responder for HbA1c treatment target without weight gain - supportive statistical analysis - full analysis set

Parameter Code=HBA7WOWG

The GENMOD Procedure

Model Information

| | | |
|--------------------|-------------|--------------------|
| Data Set | WORK.ADATA2 | |
| Distribution | Binomial | |
| Link Function | Logit | |
| Dependent Variable | AVALC | Analysis Value (C) |

| | |
|-----------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Events | 255 |
| Number of Trials | 720 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 255 |
| 2 | N | 465 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBA1CBL | | |
| Prm8 | WGTL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -443.5697 | |
| Full Log Likelihood | | -443.5697 | |
| AIC (smaller is better) | | 899.1394 | |
| AICC (smaller is better) | | 899.2572 | |
| BIC (smaller is better) | | 926.6149 | |

Algorithm converged.

Responder for HbA1c treatment target without weight gain - supportive statistical analysis - full analysis set

Parameter Code=HBA7WOWG

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald | 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|---------|-----------------------|-----------------|------------|
| Intercept | 1 | 2.8025 | 0.9850 | 0.8719 | 4.7331 | 8.09 | 0.0044 |
| trtpn 1 | 1 | -0.0231 | 0.1881 | -0.3918 | 0.3456 | 0.02 | 0.9024 |
| trtpn 2 | 1 | -1.0805 | 0.2462 | -1.5630 | -0.5979 | 19.26 | <.0001 |
| trtpn 3 | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| PREOAD2 Metformin | 1 | 0.2349 | 0.1710 | -0.1003 | 0.5701 | 1.89 | 0.1696 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| HBA1CBL | 1 | -0.3991 | 0.1024 | -0.5999 | -0.1983 | 15.18 | <.0001 |
| WGTL | 1 | 0.0004 | 0.0059 | -0.0111 | 0.0119 | 0.00 | 0.9458 |
| Scale | 0 | 1.0000 | 0.0000 | 1.0000 | 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | -0.3592 | 0.1129 | -3.18 | 0.0015 | 0.05 |
| trtpn | LSMeans frequency, IDeg | -1.4167 | 0.1942 | -7.29 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, Lira | -0.3362 | 0.1562 | -2.15 | 0.0314 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|----------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | -0.5805 | -0.1380 | 0.6982 | 0.5596 | 0.8711 |
| trtpn | LSMeans frequency, IDeg | -1.7973 | -1.0360 | 0.2425 | 0.1657 | 0.3549 |
| trtpn | LSMeans frequency, Lira | -0.6423 | -0.03007 | 0.7145 | 0.5261 | 0.9704 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.0574 | 0.2213 | 4.78 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | -0.02307 | 0.1881 | -0.12 | 0.9024 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|---------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.6237 | 1.4911 | 2.8789 |
| trtpn | Treatment odds ratio, IDegLira / Lira | -0.3918 | 0.3456 | 0.9772 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.8658 | 4.4421 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 0.6759 | 1.4129 |

11: Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes and weight gain - supportive statistical analysis - full analysis set

Parameter Code=H65WOCHY

The GENMOD Procedure

Model Information

| | | |
|--------------------|-------------|--------------------|
| Data Set | WORK.ADATA2 | |
| Distribution | Binomial | |
| Link Function | Logit | |
| Dependent Variable | AVALC | Analysis Value (C) |

| | |
|-----------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Events | 160 |
| Number of Trials | 720 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 160 |
| 2 | N | 560 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBALCBL | | |
| Prm8 | WGTBL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -359.6463 | |
| Full Log Likelihood | | -359.6463 | |
| AIC (smaller is better) | | 731.2926 | |
| AICC (smaller is better) | | 731.4104 | |
| BIC (smaller is better) | | 758.7681 | |

Algorithm converged.

Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes and weight gain - supportive statistical analysis - full analysis set

Parameter Code=H65WOCHY

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald | 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|---------|-----------------------|-----------------|------------|
| Intercept | 1 | 1.4599 | 1.1291 | -0.7530 | 3.6729 | 1.67 | 0.1960 |
| trtpn 1 | 1 | 0.4667 | 0.2232 | 0.0292 | 0.9041 | 4.37 | 0.0366 |
| trtpn 2 | 1 | -0.6089 | 0.3013 | -1.1994 | -0.0184 | 4.08 | 0.0433 |
| trtpn 3 | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| PREOAD2 Metformin | 1 | 0.4783 | 0.1912 | 0.1036 | 0.8531 | 6.26 | 0.0124 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| HBA1CBL | 1 | -0.4171 | 0.1192 | -0.6508 | -0.1833 | 12.23 | 0.0005 |
| WGTL | 1 | 0.0051 | 0.0066 | -0.0079 | 0.0181 | 0.58 | 0.4450 |
| Scale | 0 | 1.0000 | 0.0000 | 1.0000 | 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | -0.8921 | 0.1233 | -7.23 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, IDeg | -1.9677 | 0.2360 | -8.34 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, Lira | -1.3588 | 0.1911 | -7.11 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | -1.1338 | -0.6504 | 0.4098 | 0.3218 | 0.5218 |
| trtpn | LSMeans frequency, IDeg | -2.4303 | -1.5050 | 0.1398 | 0.08801 | 0.2220 |
| trtpn | LSMeans frequency, Lira | -1.7333 | -0.9843 | 0.2570 | 0.1767 | 0.3737 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.0755 | 0.2634 | 4.08 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 0.4667 | 0.2232 | 2.09 | 0.0366 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|---------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.5592 | 1.5919 | 2.9315 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 0.02919 | 0.9041 | 1.5947 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.7492 | 4.9129 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 1.0296 | 2.4698 |

Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes and weight gain - supportive statistical analysis - full analysis set

Parameter Code=HB7WOCHY

The GENMOD Procedure

Model Information

| | | |
|--------------------|-------------|--------------------|
| Data Set | WORK.ADATA2 | |
| Distribution | Binomial | |
| Link Function | Logit | |
| Dependent Variable | AVALC | Analysis Value (C) |

| | |
|-----------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Events | 241 |
| Number of Trials | 720 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Response Profile

| Ordered Value | AVALC | Total Frequency |
|---------------|-------|-----------------|
| 1 | Y | 241 |
| 2 | N | 479 |

PROC GENMOD is modeling the probability that AVALC='Y'.

Parameter Information

| Parameter | Effect | trtpn | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | trtpn | 1 | |
| Prm3 | trtpn | 2 | |
| Prm4 | trtpn | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |
| Prm7 | HBA1CBL | | |
| Prm8 | WGTL | | |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|----|-----------|----------|
| Log Likelihood | | -438.4315 | |
| Full Log Likelihood | | -438.4315 | |
| AIC (smaller is better) | | 888.8631 | |
| AICC (smaller is better) | | 888.9809 | |
| BIC (smaller is better) | | 916.3386 | |

Algorithm converged.

Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes and weight gain - supportive statistical analysis - full analysis set

Parameter Code=HB7WOCHY

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald | 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|---------|-----------------------|-----------------|------------|
| Intercept | 1 | 2.1921 | 0.9893 | 0.2532 | 4.1311 | 4.91 | 0.0267 |
| trtpn 1 | 1 | -0.1069 | 0.1890 | -0.4774 | 0.2636 | 0.32 | 0.5717 |
| trtpn 2 | 1 | -1.0692 | 0.2478 | -1.5549 | -0.5836 | 18.62 | <.0001 |
| trtpn 3 | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| PREOAD2 Metformin | 1 | 0.2598 | 0.1720 | -0.0773 | 0.5968 | 2.28 | 0.1309 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 | 0.0000 | | |
| HBA1CBL | 1 | -0.3417 | 0.1029 | -0.5433 | -0.1401 | 11.03 | 0.0009 |
| WGTL | 1 | 0.0016 | 0.0059 | -0.0100 | 0.0131 | 0.07 | 0.7916 |
| Scale | 0 | 1.0000 | 0.0000 | 1.0000 | 1.0000 | | |

NOTE: The scale parameter was held fixed.

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|-----------------------------|----------|----------------|---------|---------|-------|
| trtpn | LSMeans frequency, IDegLira | -0.4823 | 0.1139 | -4.23 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, IDeg | -1.4447 | 0.1959 | -7.37 | <.0001 | 0.05 |
| trtpn | LSMeans frequency, Lira | -0.3754 | 0.1564 | -2.40 | 0.0164 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------------------|---------|----------|---------------|---------------------|---------------------|
| trtpn | LSMeans frequency, IDegLira | -0.7056 | -0.2591 | 0.6173 | 0.4938 | 0.7718 |
| trtpn | LSMeans frequency, IDeg | -1.8286 | -1.0607 | 0.2358 | 0.1606 | 0.3462 |
| trtpn | LSMeans frequency, Lira | -0.6820 | -0.06891 | 0.6870 | 0.5056 | 0.9334 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha |
|--------|---------------------------------------|----------|----------------|---------|---------|-------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.9623 | 0.2234 | 4.31 | <.0001 | 0.05 |
| trtpn | Treatment odds ratio, IDegLira / Lira | -0.1069 | 0.1890 | -0.57 | 0.5717 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated |
|--------|---------------------------------------|---------|--------|---------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 0.5244 | 1.4002 | 2.6177 |
| trtpn | Treatment odds ratio, IDegLira / Lira | -0.4774 | 0.2636 | 0.8986 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|---------------------------------------|---------------------|---------------------|
| trtpn | Treatment odds ratio, IDegLira / IDeg | 1.6894 | 4.0562 |
| trtpn | Treatment odds ratio, IDegLira / Lira | 0.6204 | 1.3016 |

12: Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis - full analysis set

Parameter Code=C25208X

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 6.8139 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3434.3 |
| AIC (Smaller is Better) | 3436.3 |
| AICC (Smaller is Better) | 3436.3 |
| BIC (Smaller is Better) | 3440.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -1.9302 | 0.5566 | 715 | -3.47 | 0.0006 | 0.05 |
| trtpn | | 1 | 2.5706 | 0.2383 | 715 | 10.79 | <.0001 | 0.05 |
| trtpn | | 2 | 3.6551 | 0.2756 | 715 | 13.26 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6254 | 0.2084 | 715 | 3.00 | 0.0028 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.9906 | 0.007083 | 715 | 139.86 | <.0001 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|--|---|---------|---------|
| Intercept | | | -3.0230 | -0.8375 |
| trtpn | | 1 | 2.1028 | 3.0384 |
| trtpn | | 2 | 3.1140 | 4.1961 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.2162 | 1.0347 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.9767 | 1.0045 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|-----------|-----------|---------|--------|
| trtpn | 2 | 715 | 95.37 | <.0001 |
| PREOAD2 | 1 | 715 | 9.00 | 0.0028 |
| BASE | 1 | 715 | 19562.2 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 74.2782 | 0.1375 | 715 | 540.36 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 75.3627 | 0.1952 | 715 | 386.03 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 71.7076 | 0.1946 | 715 | 368.53 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 74.0083 | 74.5480 | 1.814E32 | 1.385E32 | 2.376E32 |
| trtpn | LSMeans, IDeg | 74.9794 | 75.7460 | 5.365E32 | 3.657E32 | 7.871E32 |
| trtpn | LSMeans, Lira | 71.3256 | 72.0896 | 1.387E31 | 9.469E30 | 2.033E31 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|-------------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -1.0845 | 0.2389 | 715 | -4.54 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -1.5535 | -0.6155 | 0.3381 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|------------------------|------------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.2115 | 0.5404 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
- full analysis set

Parameter Code=C25208X

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 2.5706 | 0.2383 | 715 | 10.79 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | 2.1028 | 3.0384 | 13.0733 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 8.1888 | 20.8714 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 33.1179 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4566.4 |
| AIC (Smaller is Better) | 4568.4 |
| AICC (Smaller is Better) | 4568.4 |
| BIC (Smaller is Better) | 4572.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -4.2554 | 1.2271 | 715 | -3.47 | 0.0006 | 0.05 |
| trtpn | | 1 | 5.6671 | 0.5253 | 715 | 10.79 | <.0001 | 0.05 |
| trtpn | | 2 | 8.0581 | 0.6075 | 715 | 13.26 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.3789 | 0.4595 | 715 | 3.00 | 0.0028 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.9906 | 0.007083 | 715 | 139.86 | <.0001 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|--|---|---------|---------|
| Intercept | | | -6.6645 | -1.8463 |
| trtpn | | 1 | 4.6358 | 6.6985 |
| trtpn | | 2 | 6.8653 | 9.2509 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.4766 | 2.2811 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.9767 | 1.0045 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|-----------|-----------|---------|--------|
| trtpn | 2 | 715 | 95.37 | <.0001 |
| PREOAD2 | 1 | 715 | 9.00 | 0.0028 |
| BASE | 1 | 715 | 19562.2 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 163.76 | 0.3030 | 715 | 540.36 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 166.15 | 0.4304 | 715 | 386.03 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 158.09 | 0.4290 | 715 | 368.53 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 163.16 | 164.35 | 1.312E71 | 7.238E70 | 2.379E71 |
| trtpn | LSMeans, IDeg | 165.30 | 166.99 | 1.434E72 | 6.158E71 | 3.337E72 |
| trtpn | LSMeans, Lira | 157.25 | 158.93 | 4.538E68 | 1.955E68 | 1.053E69 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|-------------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -2.3909 | 0.5267 | 715 | -4.54 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -3.4249 | -1.3570 | 0.09154 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|------------------------|------------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.03255 | 0.2574 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
- full analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 5.6671 | 0.5253 | 715 | 10.79 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | 4.6358 | 6.6985 | 289.21 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 103.11 | 811.17 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set

Parameter Code=C25208X

The Mixed Procedure

Model Information

Data Set WORK.ADATA2
 Dependent Variable CHG
 Covariance Structure Diagonal
 Estimation Method REML
 Residual Variance Method Profile
 Fixed Effects SE Method Model-Based
 Degrees of Freedom Method Residual

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

Covariance Parameters 1
 Columns in X 7
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 720

Number of Observations

Number of Observations Read 720
 Number of Observations Used 720
 Number of Observations Not Used 0

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 6.8139 |

Fit Statistics

-2 Res Log Likelihood 3434.3
 AIC (Smaller is Better) 3436.3
 AICC (Smaller is Better) 3436.3
 BIC (Smaller is Better) 3440.9

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -1.9302 | 0.5566 | 715 | -3.47 | 0.0006 | 0.05 |
| trtpn | | 1 | 2.5706 | 0.2383 | 715 | 10.79 | <.0001 | 0.05 |
| trtpn | | 2 | 3.6551 | 0.2756 | 715 | 13.26 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6254 | 0.2084 | 715 | 3.00 | 0.0028 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.00938 | 0.007083 | 715 | -1.32 | 0.1856 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|--|---|----------|----------|
| Intercept | | | -3.0230 | -0.8375 |
| trtpn | | 1 | 2.1028 | 3.0384 |
| trtpn | | 2 | 3.1140 | 4.1961 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.2162 | 1.0347 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.02329 | 0.004522 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|-----------|-----------|---------|--------|
| trtpn | 2 | 715 | 95.37 | <.0001 |
| PREOAD2 | 1 | 715 | 9.00 | 0.0028 |
| BASE | 1 | 715 | 1.76 | 0.1856 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 0.1480 | 0.1375 | 715 | 1.08 | 0.2819 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 1.2325 | 0.1952 | 715 | 6.31 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -2.4226 | 0.1946 | 715 | -12.45 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.1219 | 0.4179 |
| trtpn | Change from baseline, IDeg | 0.05 | 0.8493 | 1.6158 |
| trtpn | Change from baseline, Lira | 0.05 | -2.8046 | -2.0405 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 33.1179 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4566.4 |
| AIC (Smaller is Better) | 4568.4 |
| AICC (Smaller is Better) | 4568.4 |
| BIC (Smaller is Better) | 4572.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -4.2554 | 1.2271 | 715 | -3.47 | 0.0006 | 0.05 |
| trtpn | | 1 | 5.6671 | 0.5253 | 715 | 10.79 | <.0001 | 0.05 |
| trtpn | | 2 | 8.0581 | 0.6075 | 715 | 13.26 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.3789 | 0.4595 | 715 | 3.00 | 0.0028 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.00938 | 0.007083 | 715 | -1.32 | 0.1856 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|--|---|----------|----------|
| Intercept | | | -6.6645 | -1.8463 |
| trtpn | | 1 | 4.6358 | 6.6985 |
| trtpn | | 2 | 6.8653 | 9.2509 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.4766 | 2.2811 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.02329 | 0.004522 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|-----------|-----------|---------|--------|
| trtpn | 2 | 715 | 95.37 | <.0001 |
| PREOAD2 | 1 | 715 | 9.00 | 0.0028 |
| BASE | 1 | 715 | 1.76 | 0.1856 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 0.3263 | 0.3030 | 715 | 1.08 | 0.2819 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 2.7173 | 0.4304 | 715 | 6.31 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -5.3408 | 0.4290 | 715 | -12.45 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.2686 | 0.9213 |
| trtpn | Change from baseline, IDeg | 0.05 | 1.8723 | 3.5623 |
| trtpn | Change from baseline, Lira | 0.05 | -6.1830 | -4.4986 |

13: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C25208X

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 7.0840 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3241.1 |
| AIC (Smaller is Better) | 3243.1 |
| AICC (Smaller is Better) | 3243.1 |
| BIC (Smaller is Better) | 3247.6 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -2.1023 | 0.5882 | 669 | -3.57 | 0.0004 | 0.05 |
| trtan | | 1 | 2.7218 | 0.2548 | 669 | 10.68 | <.0001 | 0.05 |
| trtan | | 2 | 3.8575 | 0.2933 | 669 | 13.15 | <.0001 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6458 | 0.2192 | 669 | 2.95 | 0.0033 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.9910 | 0.007451 | 669 | 132.99 | <.0001 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|---------|---------|
| Intercept | | | -3.2572 | -0.9475 |
| trtan | | 1 | 2.2216 | 3.2221 |
| trtan | | 2 | 3.2817 | 4.4334 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | 0.2154 | 1.0762 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.9764 | 1.0056 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 92.95 | <.0001 |
| PREOAD2 | 1 | 669 | 8.68 | 0.0033 |
| BASE | 1 | 669 | 17686.7 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtan | LSMeans, IDegLira | WORK.ADATA2 | 74.3557 | 0.1436 | 669 | 517.92 | <.0001 | 0.05 |
| trtan | LSMeans, IDeg | WORK.ADATA2 | 75.4914 | 0.2043 | 669 | 369.57 | <.0001 | 0.05 |
| trtan | LSMeans, Lira | WORK.ADATA2 | 71.6338 | 0.2104 | 669 | 340.39 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtan | LSMeans, IDegLira | 74.0738 | 74.6376 | 1.96E32 | 1.479E32 | 2.598E32 |
| trtan | LSMeans, IDeg | 75.0903 | 75.8924 | 6.102E32 | 4.086E32 | 9.113E32 |
| trtan | LSMeans, Lira | 71.2206 | 72.0471 | 1.289E31 | 8.526E30 | 1.948E31 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -1.1357 | 0.2498 | 669 | -4.55 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtan | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -1.6262 | -0.6452 | 0.3212 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - IDeg | 0.1967 | 0.5245 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C25208X

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 2.7218 | 0.2548 | 669 | 10.68 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtan | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | 2.2216 | 3.2221 | 15.2082 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - Lira | 9.2217 | 25.0810 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 34.4308 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4300.5 |
| AIC (Smaller is Better) | 4302.5 |
| AICC (Smaller is Better) | 4302.5 |
| BIC (Smaller is Better) | 4307.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -4.6348 | 1.2967 | 669 | -3.57 | 0.0004 | 0.05 |
| trtan | | 1 | 6.0006 | 0.5617 | 669 | 10.68 | <.0001 | 0.05 |
| trtan | | 2 | 8.5044 | 0.6465 | 669 | 13.15 | <.0001 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.4238 | 0.4832 | 669 | 2.95 | 0.0033 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.9910 | 0.007451 | 669 | 132.99 | <.0001 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|---------|---------|
| Intercept | | | -7.1808 | -2.0888 |
| trtan | | 1 | 4.8977 | 7.1035 |
| trtan | | 2 | 7.2349 | 9.7739 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | 0.4750 | 2.3727 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.9764 | 1.0056 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 92.95 | <.0001 |
| PREOAD2 | 1 | 669 | 8.68 | 0.0033 |
| BASE | 1 | 669 | 17686.7 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtan | LSMeans, IDegLira | WORK.ADATA2 | 163.93 | 0.3165 | 669 | 517.92 | <.0001 | 0.05 |
| trtan | LSMeans, IDeg | WORK.ADATA2 | 166.43 | 0.4503 | 669 | 369.57 | <.0001 | 0.05 |
| trtan | LSMeans, Lira | WORK.ADATA2 | 157.93 | 0.4640 | 669 | 340.39 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtan | LSMeans, IDegLira | 163.30 | 164.55 | 1.557E71 | 8.363E70 | 2.898E71 |
| trtan | LSMeans, IDeg | 165.55 | 167.31 | 1.904E72 | 7.863E71 | 4.609E72 |
| trtan | LSMeans, Lira | 157.01 | 158.84 | 3.857E68 | 1.551E68 | 9.591E68 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -2.5038 | 0.5507 | 669 | -4.55 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtan | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -3.5850 | -1.4225 | 0.08178 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - IDeg | 0.02774 | 0.2411 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtan | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 6.0006 | 0.5617 | 669 | 10.68 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtan | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | 4.8977 | 7.1035 | 403.68 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtan | Treatment contrast, IDegLira - Lira | 133.98 | 1216.26 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C25208X

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 7.0840 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3241.1 |
| AIC (Smaller is Better) | 3243.1 |
| AICC (Smaller is Better) | 3243.1 |
| BIC (Smaller is Better) | 3247.6 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -2.1023 | 0.5882 | 669 | -3.57 | 0.0004 | 0.05 |
| trtan | | 1 | 2.7218 | 0.2548 | 669 | 10.68 | <.0001 | 0.05 |
| trtan | | 2 | 3.8575 | 0.2933 | 669 | 13.15 | <.0001 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6458 | 0.2192 | 669 | 2.95 | 0.0033 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.00902 | 0.007451 | 669 | -1.21 | 0.2267 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|----------|----------|
| Intercept | | | -3.2572 | -0.9475 |
| trtan | | 1 | 2.2216 | 3.2221 |
| trtan | | 2 | 3.2817 | 4.4334 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | 0.2154 | 1.0762 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.02365 | 0.005614 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 92.95 | <.0001 |
| PREOAD2 | 1 | 669 | 8.68 | 0.0033 |
| BASE | 1 | 669 | 1.46 | 0.2267 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtan | Change from baseline, IDegLira | WORK.ADATA2 | 0.1632 | 0.1436 | 669 | 1.14 | 0.2559 |
| trtan | Change from baseline, IDeg | WORK.ADATA2 | 1.2989 | 0.2043 | 669 | 6.36 | <.0001 |
| trtan | Change from baseline, Lira | WORK.ADATA2 | -2.5586 | 0.2104 | 669 | -12.16 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtan | Change from baseline, IDegLira | 0.05 | -0.1186 | 0.4451 |
| trtan | Change from baseline, IDeg | 0.05 | 0.8979 | 1.7000 |
| trtan | Change from baseline, Lira | 0.05 | -2.9718 | -2.1454 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtan | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 674 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 674 |
| Number of Observations Used | 674 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 34.4308 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4300.5 |
| AIC (Smaller is Better) | 4302.5 |
| AICC (Smaller is Better) | 4302.5 |
| BIC (Smaller is Better) | 4307.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -4.6348 | 1.2967 | 669 | -3.57 | 0.0004 | 0.05 |
| trtan | | 1 | 6.0006 | 0.5617 | 669 | 10.68 | <.0001 | 0.05 |
| trtan | | 2 | 8.5044 | 0.6465 | 669 | 13.15 | <.0001 | 0.05 |
| trtan | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.4238 | 0.4832 | 669 | 2.95 | 0.0033 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.00902 | 0.007451 | 669 | -1.21 | 0.2267 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - per protocol analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Actual Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|------------------------------------|----------|----------|
| Intercept | | | -7.1808 | -2.0888 |
| trtan | | 1 | 4.8977 | 7.1035 |
| trtan | | 2 | 7.2349 | 9.7739 |
| trtan | | 3 | | |
| PREOAD2 | Metformin | | 0.4750 | 2.3727 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.02365 | 0.005614 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtan | 2 | 669 | 92.95 | <.0001 |
| PREOAD2 | 1 | 669 | 8.68 | 0.0033 |
| BASE | 1 | 669 | 1.46 | 0.2267 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtan | Change from baseline, IDegLira | WORK.ADATA2 | 0.3599 | 0.3165 | 669 | 1.14 | 0.2559 |
| trtan | Change from baseline, IDeg | WORK.ADATA2 | 2.8637 | 0.4503 | 669 | 6.36 | <.0001 |
| trtan | Change from baseline, Lira | WORK.ADATA2 | -5.6407 | 0.4640 | 669 | -12.16 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtan | Change from baseline, IDegLira | 0.05 | -0.2616 | 0.9814 |
| trtan | Change from baseline, IDeg | 0.05 | 1.9794 | 3.7479 |
| trtan | Change from baseline, Lira | 0.05 | -6.5517 | -4.7297 |

14: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C25208X

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 7.1903 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3178.8 |
| AIC (Smaller is Better) | 3180.8 |
| AICC (Smaller is Better) | 3180.8 |
| BIC (Smaller is Better) | 3185.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -2.0338 | 0.5997 | 654 | -3.39 | 0.0007 | 0.05 |
| trtpn | | 1 | 2.6948 | 0.2623 | 654 | 10.27 | <.0001 | 0.05 |
| trtpn | | 2 | 3.8227 | 0.3012 | 654 | 12.69 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6288 | 0.2232 | 654 | 2.82 | 0.0050 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.9907 | 0.007605 | 654 | 130.26 | <.0001 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | -3.2114 | -0.8561 |
| trtpn | | 1 | 2.1797 | 3.2099 |
| trtpn | | 2 | 3.2313 | 4.4141 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.1905 | 1.0670 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.9757 | 1.0056 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 85.96 | <.0001 |
| PREOAD2 | 1 | 654 | 7.94 | 0.0050 |
| BASE | 1 | 654 | 16968.0 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 74.3137 | 0.1453 | 654 | 511.41 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 75.4416 | 0.2076 | 654 | 363.33 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 71.6190 | 0.2183 | 654 | 328.11 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 74.0284 | 74.5991 | 1.88E32 | 1.413E32 | 2.5E32 |
| trtpn | LSMeans, IDeg | 75.0339 | 75.8493 | 5.806E32 | 3.862E32 | 8.729E32 |
| trtpn | LSMeans, Lira | 71.1903 | 72.0476 | 1.27E31 | 8.271E30 | 1.949E31 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -1.1279 | 0.2536 | 654 | -4.45 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -1.6258 | -0.6299 | 0.3237 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.1968 | 0.5326 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C25208X

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 2.6948 | 0.2623 | 654 | 10.27 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | 2.1797 | 3.2099 | 14.8025 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 8.8438 | 24.7759 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 34.9472 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4214.4 |
| AIC (Smaller is Better) | 4216.4 |
| AICC (Smaller is Better) | 4216.4 |
| BIC (Smaller is Better) | 4220.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -4.4837 | 1.3222 | 654 | -3.39 | 0.0007 | 0.05 |
| trtpn | | 1 | 5.9410 | 0.5783 | 654 | 10.27 | <.0001 | 0.05 |
| trtpn | | 2 | 8.4275 | 0.6640 | 654 | 12.69 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.3862 | 0.4920 | 654 | 2.82 | 0.0050 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.9907 | 0.007605 | 654 | 130.26 | <.0001 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | -7.0800 | -1.8874 |
| trtpn | | 1 | 4.8055 | 7.0766 |
| trtpn | | 2 | 7.1237 | 9.7313 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.4201 | 2.3524 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.9757 | 1.0056 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 85.96 | <.0001 |
| PREOAD2 | 1 | 654 | 7.94 | 0.0050 |
| BASE | 1 | 654 | 16968.0 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 163.83 | 0.3204 | 654 | 511.41 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 166.32 | 0.4578 | 654 | 363.33 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 157.89 | 0.4812 | 654 | 328.11 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 163.20 | 164.46 | 1.419E71 | 7.567E70 | 2.663E71 |
| trtpn | LSMeans, IDeg | 165.42 | 167.22 | 1.706E72 | 6.944E71 | 4.191E72 |
| trtpn | LSMeans, Lira | 156.95 | 158.84 | 3.732E68 | 1.451E68 | 9.601E68 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -2.4865 | 0.5591 | 654 | -4.45 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -3.5843 | -1.3887 | 0.08320 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.02776 | 0.2494 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 5.9410 | 0.5783 | 654 | 10.27 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | 4.8055 | 7.0766 | 380.32 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 122.18 | 1183.89 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C25208X

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 7.1903 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3178.8 |
| AIC (Smaller is Better) | 3180.8 |
| AICC (Smaller is Better) | 3180.8 |
| BIC (Smaller is Better) | 3185.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -2.0338 | 0.5997 | 654 | -3.39 | 0.0007 | 0.05 |
| trtpn | | 1 | 2.6948 | 0.2623 | 654 | 10.27 | <.0001 | 0.05 |
| trtpn | | 2 | 3.8227 | 0.3012 | 654 | 12.69 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6288 | 0.2232 | 654 | 2.82 | 0.0050 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.00935 | 0.007605 | 654 | -1.23 | 0.2194 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|----------|
| Intercept | | | -3.2114 | -0.8561 |
| trtpn | | 1 | 2.1797 | 3.2099 |
| trtpn | | 2 | 3.2313 | 4.4141 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.1905 | 1.0670 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.02428 | 0.005584 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 85.96 | <.0001 |
| PREOAD2 | 1 | 654 | 7.94 | 0.0050 |
| BASE | 1 | 654 | 1.51 | 0.2194 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 0.1749 | 0.1453 | 654 | 1.20 | 0.2292 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 1.3028 | 0.2076 | 654 | 6.27 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -2.5199 | 0.2183 | 654 | -11.54 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.1104 | 0.4602 |
| trtpn | Change from baseline, IDeg | 0.05 | 0.8951 | 1.7105 |
| trtpn | Change from baseline, Lira | 0.05 | -2.9485 | -2.0913 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 659 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 659 |
| Number of Observations Used | 659 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 34.9472 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4214.4 |
| AIC (Smaller is Better) | 4216.4 |
| AICC (Smaller is Better) | 4216.4 |
| BIC (Smaller is Better) | 4220.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -4.4837 | 1.3222 | 654 | -3.39 | 0.0007 | 0.05 |
| trtpn | | 1 | 5.9410 | 0.5783 | 654 | 10.27 | <.0001 | 0.05 |
| trtpn | | 2 | 8.4275 | 0.6640 | 654 | 12.69 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.3862 | 0.4920 | 654 | 2.82 | 0.0050 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.00935 | 0.007605 | 654 | -1.23 | 0.2194 | 0.05 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|----------|
| Intercept | | | -7.0800 | -1.8874 |
| trtpn | | 1 | 4.8055 | 7.0766 |
| trtpn | | 2 | 7.1237 | 9.7313 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.4201 | 2.3524 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.02428 | 0.005584 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 654 | 85.96 | <.0001 |
| PREOAD2 | 1 | 654 | 7.94 | 0.0050 |
| BASE | 1 | 654 | 1.51 | 0.2194 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 0.3856 | 0.3204 | 654 | 1.20 | 0.2292 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 2.8721 | 0.4578 | 654 | 6.27 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -5.5554 | 0.4812 | 654 | -11.54 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.2435 | 1.0146 |
| trtpn | Change from baseline, IDeg | 0.05 | 1.9733 | 3.7710 |
| trtpn | Change from baseline, Lira | 0.05 | -6.5003 | -4.6105 |

15: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | AVAL |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| avisitn | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Class Level Information

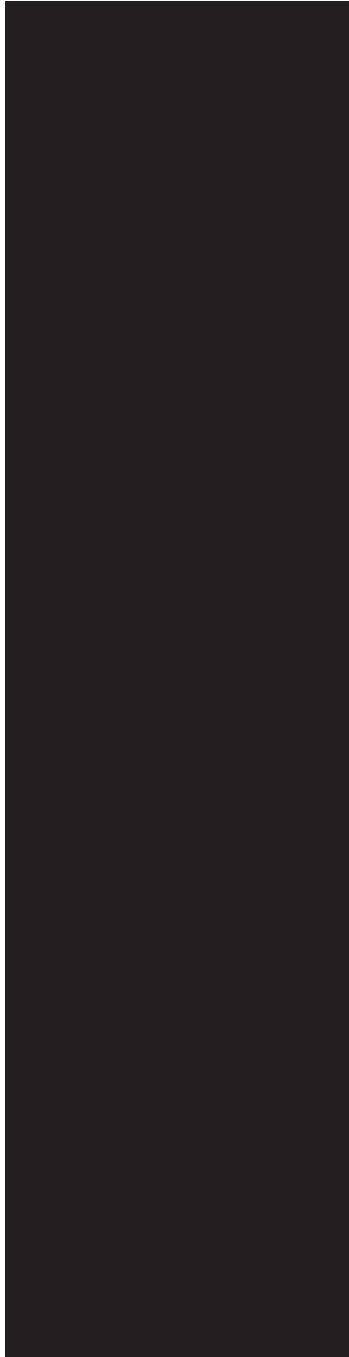
| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4046 |
| Number of Observations Not Used | 274 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 17548.36814718 | |
| 1 | 2 | 13253.73696060 | 0.00000775 |
| 2 | 1 | 13253.71397046 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|---------|
| -2 Res Log Likelihood | 13253.7 |
| AIC (Smaller is Better) | 13295.7 |
| AICC (Smaller is Better) | 13295.9 |
| BIC (Smaller is Better) | 13391.9 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 4294.65 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|------------------|--------|--------|---------|--------|
| TRT01PN(avisitn) | 12 | 814 | 20.33 | <.0001 |
| PREOAD2(avisitn) | 6 | 674 | 2.75 | 0.0120 |
| BASE(avisitn) | 6 | 676 | 12856.3 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|------------------|-------------------|---------------|----------|----------------|-------|---------|---------|
| TRT01PN(avisitn) | LSMeans, IDegLira | WORK.ANA_DATA | 74.3474 | 0.1440 | 672.4 | 516.20 | <.0001 |
| TRT01PN(avisitn) | LSMeans, IDeg | WORK.ANA_DATA | 75.4830 | 0.2052 | 675.4 | 367.88 | <.0001 |
| TRT01PN(avisitn) | LSMeans, Lira | WORK.ANA_DATA | 71.6194 | 0.2118 | 698.6 | 338.12 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|------------------|-------------------|-------|---------|---------|
| TRT01PN(avisitn) | LSMeans, IDegLira | 0.05 | 74.0646 | 74.6302 |
| TRT01PN(avisitn) | LSMeans, IDeg | 0.05 | 75.0801 | 75.8858 |
| TRT01PN(avisitn) | LSMeans, Lira | 0.05 | 71.2035 | 72.0353 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | AVAL |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| avisitn | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

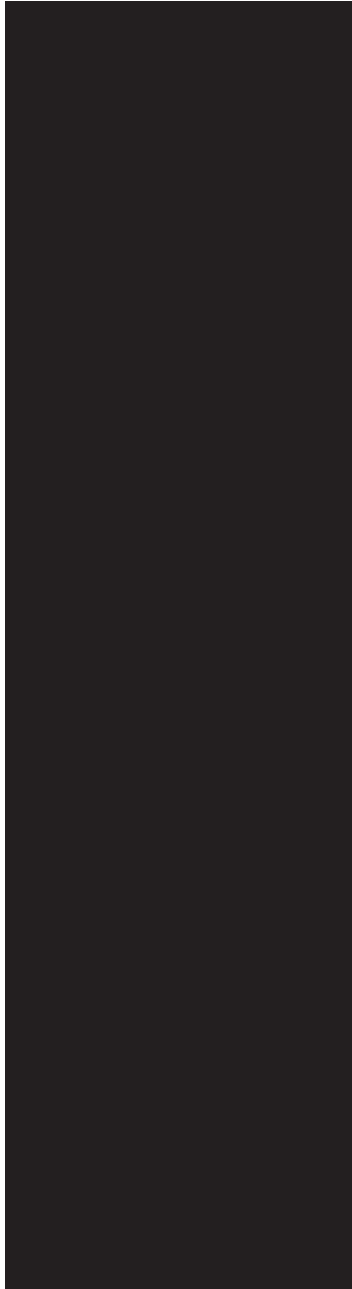
Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Class Level Information

| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

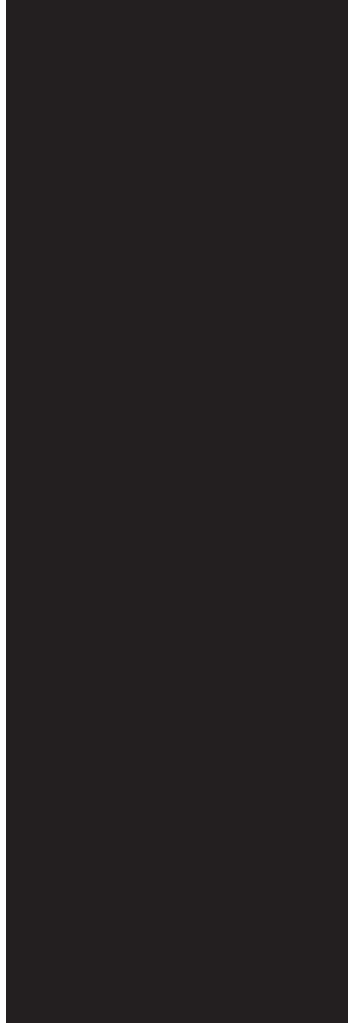
The Mixed Procedure



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4046 |
| Number of Observations Not Used | 274 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 23907.60340805 | |
| 1 | 2 | 19612.97222150 | 0.00000372 |
| 2 | 1 | 19612.94923134 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|---------|
| -2 Res Log Likelihood | 19612.9 |
| AIC (Smaller is Better) | 19654.9 |
| AICC (Smaller is Better) | 19655.2 |
| BIC (Smaller is Better) | 19751.1 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 4294.65 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-------------------|--------|--------|---------|--------|
| TRT01PN (avisitn) | 12 | 814 | 20.33 | <.0001 |
| PREOAD2 (avisitn) | 6 | 674 | 2.75 | 0.0120 |
| BASE (avisitn) | 6 | 676 | 12856.3 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|------------------|-------------------|---------------|----------|----------------|-------|---------|---------|
| TRT01PN(avisitn) | LSMeans, IDegLira | WORK.ANA_DATA | 163.91 | 0.3175 | 672.4 | 516.20 | <.0001 |
| TRT01PN(avisitn) | LSMeans, IDeg | WORK.ANA_DATA | 166.41 | 0.4524 | 675.4 | 367.88 | <.0001 |
| TRT01PN(avisitn) | LSMeans, Lira | WORK.ANA_DATA | 157.89 | 0.4670 | 698.6 | 338.12 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|------------------|-------------------|-------|--------|--------|
| TRT01PN(avisitn) | LSMeans, IDegLira | 0.05 | 163.28 | 164.53 |
| TRT01PN(avisitn) | LSMeans, IDeg | 0.05 | 165.52 | 167.30 |
| TRT01PN(avisitn) | LSMeans, Lira | 0.05 | 156.98 | 158.81 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | CHG |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| avisitn | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Class Level Information

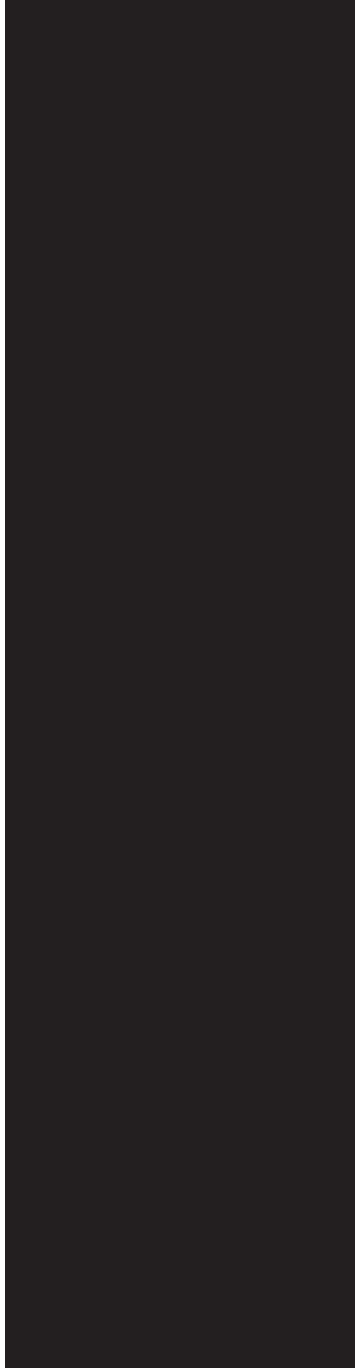
| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4046 |
| Number of Observations Not Used | 274 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 17548.36814717 | |
| 1 | 2 | 13253.73696060 | 0.00000775 |
| 2 | 1 | 13253.71397046 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|---------|
| -2 Res Log Likelihood | 13253.7 |
| AIC (Smaller is Better) | 13295.7 |
| AICC (Smaller is Better) | 13295.9 |
| BIC (Smaller is Better) | 13391.9 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 4294.65 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-------------------|--------|--------|---------|--------|
| TRT01PN (avisitn) | 12 | 814 | 20.33 | <.0001 |
| PREOAD2 (avisitn) | 6 | 674 | 2.75 | 0.0120 |
| BASE (avisitn) | 6 | 676 | 6.16 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|------------------|--------------------------------|---------------|----------|----------------|-------|---------|
| TRT01PN(avisitn) | Change from baseline, IDegLira | WORK.ANA_DATA | 0.1582 | 0.1440 | 672.4 | 1.10 |
| TRT01PN(avisitn) | Change from baseline, IDeg | WORK.ANA_DATA | 1.2938 | 0.2052 | 675.4 | 6.31 |
| TRT01PN(avisitn) | Change from baseline, Lira | WORK.ANA_DATA | -2.5698 | 0.2118 | 698.6 | -12.13 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper |
|------------------|--------------------------------|---------|-------|---------|---------|
| TRT01PN(avisitn) | Change from baseline, IDegLira | 0.2725 | 0.05 | -0.1246 | 0.4410 |
| TRT01PN(avisitn) | Change from baseline, IDeg | <.0001 | 0.05 | 0.8909 | 1.6967 |
| TRT01PN(avisitn) | Change from baseline, Lira | <.0001 | 0.05 | -2.9857 | -2.1539 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF |
|------------------|-------------------------------------|---------------|----------|----------------|-------|
| TRT01PN(avisitn) | Treatment contrast, IDegLira - IDeg | WORK.ANA_DATA | -1.1356 | 0.2508 | 674.4 |
| TRT01PN(avisitn) | Treatment contrast, IDegLira - Lira | WORK.ANA_DATA | 2.7280 | 0.2562 | 690.4 |

Least Squares Means Estimates

| Effect | Label | t Value | Pr > t | Alpha | Lower | Upper |
|------------------|-------------------------------------|---------|---------|-------|---------|---------|
| TRT01PN(avisitn) | Treatment contrast, IDegLira - IDeg | -4.53 | <.0001 | 0.05 | -1.6281 | -0.6431 |
| TRT01PN(avisitn) | Treatment contrast, IDegLira - Lira | 10.65 | <.0001 | 0.05 | 2.2250 | 3.2310 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Model Information

| | |
|---------------------------|---------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | CHG |
| Covariance Structure | Unstructured |
| Subject Effect | SUBJID |
| Estimation Method | REML |
| Residual Variance Method | None |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Satterthwaite |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRT01PN | 3 | 1 2 3 |
| avisitn | 6 | 60 100 140 180 220 280 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Class Level Information

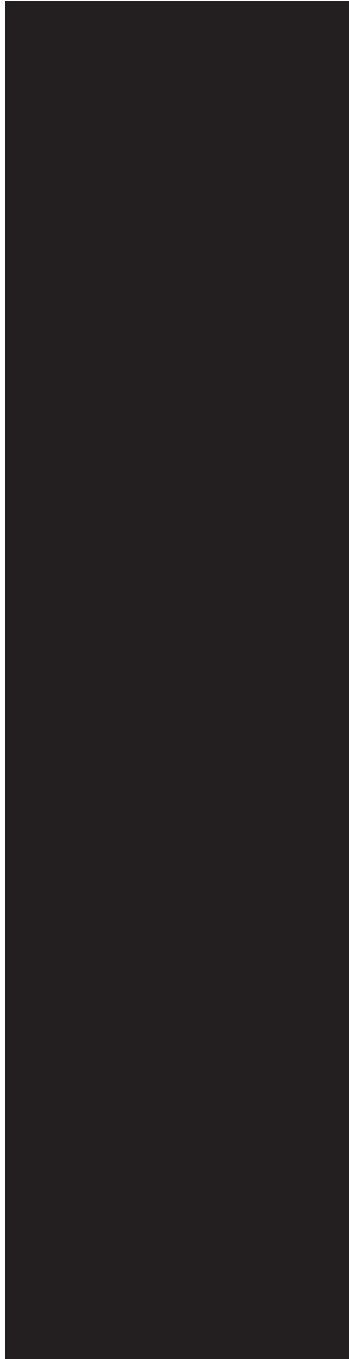
| Class | Levels | Values |
|--------|--------|--------|
| SUBJID | 720 | |



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure



Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 21 |
| Columns in X | 37 |
| Columns in Z | 0 |
| Subjects | 720 |
| Max Obs per Subject | 6 |

Number of Observations

| | |
|---------------------------------|------|
| Number of Observations Read | 4320 |
| Number of Observations Used | 4046 |
| Number of Observations Not Used | 274 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 23907.60340805 | |
| 1 | 2 | 19612.97222148 | 0.00000372 |
| 2 | 1 | 19612.94923134 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate |
|----------|---------|----------|
| UN(1,1) | SUBJID | |
| UN(2,1) | SUBJID | |
| UN(2,2) | SUBJID | |
| UN(3,1) | SUBJID | |
| UN(3,2) | SUBJID | |
| UN(3,3) | SUBJID | |
| UN(4,1) | SUBJID | |
| UN(4,2) | SUBJID | |
| UN(4,3) | SUBJID | |
| UN(4,4) | SUBJID | |
| UN(5,1) | SUBJID | |
| UN(5,2) | SUBJID | |
| UN(5,3) | SUBJID | |
| UN(5,4) | SUBJID | |
| UN(5,5) | SUBJID | |
| UN(6,1) | SUBJID | |
| UN(6,2) | SUBJID | |
| UN(6,3) | SUBJID | |
| UN(6,4) | SUBJID | |
| UN(6,5) | SUBJID | |
| UN(6,6) | SUBJID | |

Fit Statistics

| | |
|--------------------------|---------|
| -2 Res Log Likelihood | 19612.9 |
| AIC (Smaller is Better) | 19654.9 |
| AICC (Smaller is Better) | 19655.2 |
| BIC (Smaller is Better) | 19751.1 |

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 20 | 4294.65 | <.0001 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-------------------|--------|--------|---------|--------|
| TRT01PN (avisitn) | 12 | 814 | 20.33 | <.0001 |
| PREOAD2 (avisitn) | 6 | 674 | 2.75 | 0.0120 |
| BASE (avisitn) | 6 | 676 | 6.16 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|------------------|--------------------------------|---------------|----------|----------------|-------|---------|
| TRT01PN(avisitn) | Change from baseline, IDegLira | WORK.ANA_DATA | 0.3487 | 0.3175 | 672.4 | 1.10 |
| TRT01PN(avisitn) | Change from baseline, IDeg | WORK.ANA_DATA | 2.8523 | 0.4524 | 675.4 | 6.31 |
| TRT01PN(avisitn) | Change from baseline, Lira | WORK.ANA_DATA | -5.6654 | 0.4670 | 698.6 | -12.13 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper |
|------------------|--------------------------------|---------|-------|---------|---------|
| TRT01PN(avisitn) | Change from baseline, IDegLira | 0.2725 | 0.05 | -0.2747 | 0.9722 |
| TRT01PN(avisitn) | Change from baseline, IDeg | <.0001 | 0.05 | 1.9641 | 3.7405 |
| TRT01PN(avisitn) | Change from baseline, Lira | <.0001 | 0.05 | -6.5822 | -4.7486 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF |
|------------------|-------------------------------------|---------------|----------|----------------|-------|
| TRT01PN(avisitn) | Treatment contrast, IDegLira - IDeg | WORK.ANA_DATA | -2.5035 | 0.5530 | 674.4 |
| TRT01PN(avisitn) | Treatment contrast, IDegLira - Lira | WORK.ANA_DATA | 6.0142 | 0.5648 | 690.4 |

Least Squares Means Estimates

| Effect | Label | t Value | Pr > t | Alpha | Lower | Upper |
|------------------|-------------------------------------|---------|---------|-------|---------|---------|
| TRT01PN(avisitn) | Treatment contrast, IDegLira - IDeg | -4.53 | <.0001 | 0.05 | -3.5893 | -1.4177 |
| TRT01PN(avisitn) | Treatment contrast, IDegLira - Lira | 10.65 | <.0001 | 0.05 | 4.9052 | 7.1231 |

16: Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=12 Parameter Code=C25208X Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.002049 | 0.040243 | 0.042294 | 424717 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050971 | 0.048503 | 0.999951 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 75.432878 | 0.205654 | 75.02980 | 75.83595 | 424717 | 75.291050 | 75.598927 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 366.79 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=12 Parameter Code=C25208X Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000903 | 0.019951 | 0.020855 | 531569 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.045316 | 0.043355 | 0.999957 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 74.335940 | 0.144413 | 74.05290 | 74.61899 | 531569 | 74.250861 | 74.416588 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 514.74 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=12 Parameter Code=C25208X Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.005256 | 0.039976 | 0.045238 | 73847 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.131619 | 0.116334 | 0.999884 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | 71.554362 | 0.212692 | 71.13749 | 71.97124 | 73847 | 71.264993 | 71.786081 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 336.42 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=22 Parameter Code=WEIGHTU Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.009960 | 0.195593 | 0.205563 | 424717 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050971 | 0.048503 | 0.999951 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | 166.301030 | 0.453390 | 165.4124 | 167.1897 | 424717 | 165.988353 | 166.667105 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 366.79 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=22 Parameter Code=WEIGHTU Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.004390 | 0.096969 | 0.101364 | 531569 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.045316 | 0.043355 | 0.999957 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | 163.882696 | 0.318376 | 163.2587 | 164.5067 | 531569 | 163.695128 | 164.060492 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 514.74 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=22 Parameter Code=WEIGHTU Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.025548 | 0.194299 | 0.219873 | 73847 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.131619 | 0.116334 | 0.999884 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|-------|------------|------------|
| Estimate | 157.750364 | 0.468906 | 156.8313 | 158.6694 | 73847 | 157.112416 | 158.261218 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 336.42 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=12 Parameter Code=C25208X Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|-------------------|
| Data Set | WORK.LSME_CHG_MI2 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.002049 | 0.040243 | 0.042294 | 424717 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050971 | 0.048503 | 0.999951 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 1.302740 | 0.205654 | 0.899663 | 1.705816 | 424717 | 1.160912 | 1.468788 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 6.33 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=12 Parameter Code=C25208X Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000903 | 0.019951 | 0.020855 | 531569 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.045316 | 0.043355 | 0.999957 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 0.205802 | 0.144413 | -0.07724 | 0.488847 | 531569 | 0.120722 | 0.286449 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 1.43 | 0.1541 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=12 Parameter Code=C25208X Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|-------------------|
| Data Set | WORK.LSME_CHG_MI2 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.005256 | 0.039976 | 0.045238 | 73847 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.131619 | 0.116334 | 0.999884 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -2.575777 | 0.212692 | -2.99265 | -2.15890 | 73847 | -2.865146 | -2.344058 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -12.11 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=12 Parameter Code=C25208X Label=Treatment contrast, IDegLira - IDeg

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.002813 | 0.060258 | 0.063074 | 501172 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.046733 | 0.044651 | 0.999955 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -1.096938 | 0.251145 | -1.58917 | -0.60470 | 501172 | -1.276007 | -0.942857 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -4.37 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=22 Parameter Code=WEIGHTU Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.009960 | 0.195593 | 0.205563 | 424717 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050971 | 0.048503 | 0.999951 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 2.872049 | 0.453390 | 1.983418 | 3.760680 | 424717 | 2.559372 | 3.238123 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 6.33 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=22 Parameter Code=WEIGHTU Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.004390 | 0.096969 | 0.101364 | 531569 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.045316 | 0.043355 | 0.999957 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 0.453715 | 0.318376 | -0.17029 | 1.077723 | 531569 | 0.266147 | 0.631511 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 1.43 | 0.1541 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=22 Parameter Code=WEIGHTU Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|-------------------|
| Data Set | WORK.LSME_CHG_MI2 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.025548 | 0.194299 | 0.219873 | 73847 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.131619 | 0.116334 | 0.999884 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -5.678617 | 0.468906 | -6.59767 | -4.75956 | 73847 | -6.316565 | -5.167763 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | -12.11 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=22 Parameter Code=WEIGHTU Label=Treatment contrast, IDegLira - IDeg

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.013673 | 0.292875 | 0.306562 | 501172 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.046733 | 0.044651 | 0.999955 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | -2.418334 | 0.553680 | -3.50353 | -1.33314 | 501172 | -2.813114 | -2.078643 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -4.37 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=13 Parameter Code=C25208X Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.002050 | 0.040747 | 0.042799 | 434662 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050355 | 0.047945 | 0.999952 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 75.434346 | 0.206879 | 75.02887 | 75.83982 | 434662 | 75.292957 | 75.599366 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 364.63 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=13 Parameter Code=C25208X Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000985 | 0.020201 | 0.021187 | 461469 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.048798 | 0.046532 | 0.999953 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|--------|-----------|-----------|
| Estimate | 74.184327 | 0.145558 | 73.89904 | 74.46962 | 461469 | 74.065477 | 74.270842 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 509.66 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=13 Parameter Code=C25208X Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|-------------------|
| Data Set | WORK.LSME_ABS_MI3 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.005262 | 0.040478 | 0.045745 | 75344 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.130133 | 0.115172 | 0.999885 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | 71.554942 | 0.213881 | 71.13574 | 71.97415 | 75344 | 71.265539 | 71.787147 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 334.56 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=23 Parameter Code=WEIGHTU Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.009963 | 0.198046 | 0.208018 | 434662 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050355 | 0.047945 | 0.999952 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | 166.304265 | 0.456090 | 165.4103 | 167.1982 | 434662 | 165.992557 | 166.668072 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 364.63 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=23 Parameter Code=WEIGHTU Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.004786 | 0.098185 | 0.102976 | 461469 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.048798 | 0.046532 | 0.999953 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|--------|------------|------------|
| Estimate | 163.548445 | 0.320899 | 162.9195 | 164.1774 | 461469 | 163.286426 | 163.739178 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 509.66 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=23 Parameter Code=WEIGHTU Label=LSMeans, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.025576 | 0.196735 | 0.222337 | 75344 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.130133 | 0.115172 | 0.999885 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|------------|-----------|-----------------------|----------|-------|------------|------------|
| Estimate | 157.751645 | 0.471526 | 156.8275 | 158.6758 | 75344 | 157.113619 | 158.263568 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 334.56 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=13 Parameter Code=C25208X Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.002050 | 0.040747 | 0.042799 | 434662 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050355 | 0.047945 | 0.999952 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 1.304207 | 0.206879 | 0.898730 | 1.709683 | 434662 | 1.162818 | 1.469227 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 6.30 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=13 Parameter Code=C25208X Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000985 | 0.020201 | 0.021187 | 461469 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.048798 | 0.046532 | 0.999953 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|-----------|----------|
| Estimate | 0.054188 | 0.145558 | -0.23110 | 0.339476 | 461469 | -0.064662 | 0.140703 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 0.37 | 0.7097 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=13 Parameter Code=C25208X Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.005262 | 0.040478 | 0.045745 | 75344 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.130133 | 0.115172 | 0.999885 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -2.575196 | 0.213881 | -2.99440 | -2.15599 | 75344 | -2.864600 | -2.342992 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -12.04 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=13 Parameter Code=C25208X Label=Treatment contrast, IDegLira - Lira

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.006210 | 0.060701 | 0.066917 | 115773 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.102405 | 0.092908 | 0.999907 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 2.629384 | 0.258683 | 2.122370 | 3.136398 | 115773 | 2.405082 | 2.939673 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 10.16 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=23 Parameter Code=WEIGHTU Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.009963 | 0.198046 | 0.208018 | 434662 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.050355 | 0.047945 | 0.999952 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 2.875284 | 0.456090 | 1.981361 | 3.769207 | 434662 | 2.563576 | 3.239091 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 6.30 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=23 Parameter Code=WEIGHTU Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.004786 | 0.098185 | 0.102976 | 461469 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.048798 | 0.046532 | 0.999953 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|-----------|----------|
| Estimate | 0.119464 | 0.320899 | -0.50949 | 0.748417 | 461469 | -0.142555 | 0.310196 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 0.37 | 0.7097 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=23 Parameter Code=WEIGHTU Label=Change from baseline, Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.025576 | 0.196735 | 0.222337 | 75344 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.130133 | 0.115172 | 0.999885 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|-----------|-----------|-----------------------|----------|-------|-----------|-----------|
| Estimate | -5.677336 | 0.471526 | -6.60153 | -4.75315 | 75344 | -6.315363 | -5.165413 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | -12.04 | <.0001 |

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - conditional multiple imputation - full analysis set

param_ana_sort=23 Parameter Code=WEIGHTU Label=Treatment contrast, IDegLira - Lira

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.030182 | 0.295027 | 0.325239 | 115773 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.102405 | 0.092908 | 0.999907 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 5.796800 | 0.570298 | 4.679026 | 6.914575 | 115773 | 5.302299 | 6.480870 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 10.16 | <.0001 |

17: Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=MEANWAIC

The Mixed Procedure

Model Information

Data Set WORK.ADATA2
 Dependent Variable AVAL
 Covariance Structure Diagonal
 Estimation Method REML
 Residual Variance Method Profile
 Fixed Effects SE Method Model-Based
 Degrees of Freedom Method Residual

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

Covariance Parameters 1
 Columns in X 7
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 717

Number of Observations

Number of Observations Read 720
 Number of Observations Used 717
 Number of Observations Not Used 3

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 12.8901 |

Fit Statistics

-2 Res Log Likelihood 3873.2
 AIC (Smaller is Better) 3875.2
 AICC (Smaller is Better) 3875.3
 BIC (Smaller is Better) 3879.8

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.4327 | 1.3030 | 712 | 3.40 | 0.0007 | 0.05 |
| trtpn | | 1 | 2.4135 | 0.3281 | 712 | 7.36 | <.0001 | 0.05 |
| trtpn | | 2 | 3.8648 | 0.3795 | 712 | 10.18 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6340 | 0.2863 | 712 | 2.21 | 0.0271 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.9234 | 0.01353 | 712 | 68.27 | <.0001 | 0.05 |

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=MEANWAIC

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|--------|
| Intercept | | | 1.8746 | 6.9908 |
| trtpn | | 1 | 1.7693 | 3.0578 |
| trtpn | | 2 | 3.1197 | 4.6099 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.07184 | 1.1961 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.8968 | 0.9499 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 712 | 53.53 | <.0001 |
| PREOAD2 | 1 | 712 | 4.90 | 0.0271 |
| BASE | 1 | 712 | 4660.89 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 94.6036 | 0.1896 | 712 | 498.98 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 96.0549 | 0.2692 | 712 | 356.83 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 92.1901 | 0.2677 | 712 | 344.41 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 94.2314 | 94.9758 | 1.218E41 | 8.398E40 | 1.768E41 |
| trtpn | LSMeans, IDeg | 95.5264 | 96.5834 | 5.201E41 | 3.066E41 | 8.823E41 |
| trtpn | LSMeans, Lira | 91.6645 | 92.7156 | 1.091E40 | 6.448E39 | 1.844E40 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -1.4513 | 0.3294 | 712 | -4.41 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -2.0980 | -0.8046 | 0.2343 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.1227 | 0.4473 |

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=MEANWAIC

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 2.4135 | 0.3281 | 712 | 7.36 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | 1.7693 | 3.0578 | 11.1735 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 5.8669 | 21.2799 |

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=MEANWAIC

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 717 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 717 |
| Number of Observations Not Used | 3 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 12.8901 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3873.2 |
| AIC (Smaller is Better) | 3875.2 |
| AICC (Smaller is Better) | 3875.3 |
| BIC (Smaller is Better) | 3879.8 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 4.4327 | 1.3030 | 712 | 3.40 | 0.0007 | 0.05 |
| trtpn | | 1 | 2.4135 | 0.3281 | 712 | 7.36 | <.0001 | 0.05 |
| trtpn | | 2 | 3.8648 | 0.3795 | 712 | 10.18 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6340 | 0.2863 | 712 | 2.21 | 0.0271 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.07661 | 0.01353 | 712 | -5.66 | <.0001 | 0.05 |

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=MEANWAIC

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|----------|
| Intercept | | | 1.8746 | 6.9908 |
| trtpn | | 1 | 1.7693 | 3.0578 |
| trtpn | | 2 | 3.1197 | 4.6099 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.07184 | 1.1961 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.1032 | -0.05005 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 712 | 53.53 | <.0001 |
| PREOAD2 | 1 | 712 | 4.90 | 0.0271 |
| BASE | 1 | 712 | 32.08 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -0.2104 | 0.1896 | 712 | -1.11 | 0.2674 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 1.2408 | 0.2692 | 712 | 4.61 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -2.6240 | 0.2677 | 712 | -9.80 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.5827 | 0.1618 |
| trtpn | Change from baseline, IDeg | 0.05 | 0.7123 | 1.7693 |
| trtpn | Change from baseline, Lira | 0.05 | -3.1495 | -2.0985 |

18: Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C105585P

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2.7090 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2763.3 |
| AIC (Smaller is Better) | 2765.3 |
| AICC (Smaller is Better) | 2765.3 |
| BIC (Smaller is Better) | 2769.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 6.7293 | 0.3170 | 713 | 21.23 | <.0001 | 0.05 |
| trtpn | | 1 | -1.8662 | 0.1503 | 713 | -12.42 | <.0001 | 0.05 |
| trtpn | | 2 | -1.4011 | 0.1742 | 713 | -8.04 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3263 | 0.1311 | 713 | -2.49 | 0.0130 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1393 | 0.03019 | 713 | 4.61 | <.0001 | 0.05 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C105585P

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|----------|
| Intercept | | | 6.1069 | 7.3516 |
| trtpn | | 1 | -2.1612 | -1.5712 |
| trtpn | | 2 | -1.7431 | -1.0591 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5837 | -0.06898 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.08005 | 0.1986 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 77.73 | <.0001 |
| PREOAD2 | 1 | 713 | 6.20 | 0.0130 |
| BASE | 1 | 713 | 21.29 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 6.1008 | 0.08676 | 713 | 70.32 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 6.5659 | 0.1235 | 713 | 53.17 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 7.9670 | 0.1227 | 713 | 64.92 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 5.9305 | 6.2712 | 446.22 | 376.34 | 529.09 |
| trtpn | LSMeans, IDeg | 6.3235 | 6.8084 | 710.47 | 557.51 | 905.40 |
| trtpn | LSMeans, Lira | 7.7261 | 8.2080 | 2884.34 | 2266.80 | 3670.11 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.4651 | 0.1510 | 713 | -3.08 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0021 | 0.05 | -0.7615 | -0.1687 | 0.6281 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.4670 | 0.8447 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C105585P

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -1.8662 | 0.1503 | 713 | -12.42 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -2.1612 | -1.5712 | 0.1547 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.1152 | 0.2078 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=FPGU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 879.68 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 6892.3 |
| AIC (Smaller is Better) | 6894.3 |
| AICC (Smaller is Better) | 6894.3 |
| BIC (Smaller is Better) | 6898.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 121.26 | 5.7125 | 713 | 21.23 | <.0001 | 0.05 |
| trtpn | | 1 | -33.6294 | 2.7077 | 713 | -12.42 | <.0001 | 0.05 |
| trtpn | | 2 | -25.2482 | 3.1389 | 713 | -8.04 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -5.8804 | 2.3620 | 713 | -2.49 | 0.0130 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1393 | 0.03019 | 713 | 4.61 | <.0001 | 0.05 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=FPGU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|----------|
| Intercept | | | 110.05 | 132.48 |
| trtpn | | 1 | -38.9455 | -28.3134 |
| trtpn | | 2 | -31.4108 | -19.0856 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -10.5177 | -1.2431 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.08005 | 0.1986 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 77.73 | <.0001 |
| PREOAD2 | 1 | 713 | 6.20 | 0.0130 |
| BASE | 1 | 713 | 21.29 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 109.94 | 1.5634 | 713 | 70.32 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 118.32 | 2.2253 | 713 | 53.17 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 143.57 | 2.2113 | 713 | 64.92 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 106.87 | 113.01 | 5.558E47 | 2.582E46 | 1.197E49 |
| trtpn | LSMeans, IDeg | 113.95 | 122.69 | 2.426E51 | 3.072E49 | 1.916E53 |
| trtpn | LSMeans, Lira | 139.22 | 147.91 | 2.239E62 | 2.914E60 | 1.72E64 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -8.3812 | 2.7204 | 713 | -3.08 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0021 | 0.05 | -13.7223 | -3.0402 | 0.000229 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 1.098E-6 | 0.04782 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=FPGU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -33.6294 | 2.7077 | 713 | -12.42 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|----------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -38.9455 | -28.3134 | 2.48E-15 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 1.22E-17 | 5.05E-13 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C105585P

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2.7090 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2763.3 |
| AIC (Smaller is Better) | 2765.3 |
| AICC (Smaller is Better) | 2765.3 |
| BIC (Smaller is Better) | 2769.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 6.7293 | 0.3170 | 713 | 21.23 | <.0001 | 0.05 |
| trtpn | | 1 | -1.8662 | 0.1503 | 713 | -12.42 | <.0001 | 0.05 |
| trtpn | | 2 | -1.4011 | 0.1742 | 713 | -8.04 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.3263 | 0.1311 | 713 | -2.49 | 0.0130 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8607 | 0.03019 | 713 | -28.50 | <.0001 | 0.05 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C105585P

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|----------|
| Intercept | | | 6.1069 | 7.3516 |
| trtpn | | 1 | -2.1612 | -1.5712 |
| trtpn | | 2 | -1.7431 | -1.0591 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5837 | -0.06898 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.9199 | -0.8014 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 77.73 | <.0001 |
| PREOAD2 | 1 | 713 | 6.20 | 0.0130 |
| BASE | 1 | 713 | 812.50 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -3.5461 | 0.08676 | 713 | -40.87 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -3.0810 | 0.1235 | 713 | -24.95 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -1.6799 | 0.1227 | 713 | -13.69 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -3.7164 | -3.3758 |
| trtpn | Change from baseline, IDeg | 0.05 | -3.3235 | -2.8386 |
| trtpn | Change from baseline, Lira | 0.05 | -1.9208 | -1.4390 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=FPGU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 879.68 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 6892.3 |
| AIC (Smaller is Better) | 6894.3 |
| AICC (Smaller is Better) | 6894.3 |
| BIC (Smaller is Better) | 6898.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 121.26 | 5.7125 | 713 | 21.23 | <.0001 | 0.05 |
| trtpn | | 1 | -33.6294 | 2.7077 | 713 | -12.42 | <.0001 | 0.05 |
| trtpn | | 2 | -25.2482 | 3.1389 | 713 | -8.04 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -5.8804 | 2.3620 | 713 | -2.49 | 0.0130 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8607 | 0.03019 | 713 | -28.50 | <.0001 | 0.05 |

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=FPGU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|----------|
| Intercept | | | 110.05 | 132.48 |
| trtpn | | 1 | -38.9455 | -28.3134 |
| trtpn | | 2 | -31.4108 | -19.0856 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -10.5177 | -1.2431 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.9199 | -0.8014 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 77.73 | <.0001 |
| PREOAD2 | 1 | 713 | 6.20 | 0.0130 |
| BASE | 1 | 713 | 812.50 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -63.9010 | 1.5634 | 713 | -40.87 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -55.5197 | 2.2253 | 713 | -24.95 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -30.2715 | 2.2113 | 713 | -13.69 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| trtpn | Change from baseline, IDegLira | 0.05 | -66.9703 | -60.8317 |
| trtpn | Change from baseline, IDeg | 0.05 | -59.8887 | -51.1508 |
| trtpn | Change from baseline, Lira | 0.05 | -34.6130 | -25.9300 |

19: 9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | AVAL |
| Covariance Structure | Compound Symmetry |
| Subject Effect | USUBJID |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Kenward-Roger |
| Degrees of Freedom Method | Kenward-Roger |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Number of Observations

Number of Observations Read 6480
 Number of Observations Used 6401
 Number of Observations Not Used 79

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 28226.72908143 | |
| 1 | 2 | 26184.01976519 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate | Standard Error | Z Value | Pr > Z | Alpha | Lower | Upper |
|----------|---------|----------|----------------|---------|--------|-------|--------|--------|
| CS | USUBJID | 2.0262 | 0.1238 | 16.37 | <.0001 | 0.05 | 1.7835 | 2.2688 |
| Residual | | 2.7716 | 0.05215 | 53.15 | <.0001 | 0.05 | 2.6721 | 2.8767 |

Asymptotic Covariance Matrix of Estimates

| Row | Cov Parm | CovP1 | CovP2 |
|-----|----------|----------|----------|
| 1 | CS | 0.01533 | -0.00031 |
| 2 | Residual | -0.00031 | 0.002720 |

Fit Statistics

-2 Res Log Likelihood 26184.0
 AIC (Smaller is Better) 26188.0
 AICC (Smaller is Better) 26188.0
 BIC (Smaller is Better) 26197.2

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 1 | 2042.71 | <.0001 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Estimate | Standard Error | DF | t Value | Pr > t |
|--------------|------------------------------------|-------------------------------------|------------------------|----------|----------------|------|---------|---------|
| Intercept | | | | 7.1788 | 0.1737 | 2673 | 41.34 | <.0001 |
| TRTPN | | 1 | | -1.6069 | 0.2005 | 2664 | -8.02 | <.0001 |
| TRTPN | | 2 | | -1.4114 | 0.2316 | 2655 | -6.09 | <.0001 |
| TRTPN | | 3 | | 0 | | | | |
| TRTPN(ATPTN) | | 1 | 1 | 0.05534 | 0.1385 | 5650 | 0.40 | 0.6895 |
| TRTPN(ATPTN) | | 2 | 1 | 0.1714 | 0.1858 | 5649 | 0.92 | 0.3565 |
| TRTPN(ATPTN) | | 3 | 1 | 0.03570 | 0.1866 | 5650 | 0.19 | 0.8483 |
| TRTPN(ATPTN) | | 1 | 2 | 3.7916 | 0.1387 | 5650 | 27.34 | <.0001 |
| TRTPN(ATPTN) | | 2 | 2 | 4.4526 | 0.1868 | 5654 | 23.83 | <.0001 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Estimate | Standard Error | DF | t Value | Pr > t |
|-----------------|------------------------------------|-------------------------------------|------------------------|----------|----------------|------|---------|---------|
| TRTPN (ATPTN) | | 3 | 2 | 3.4643 | 0.1873 | 5652 | 18.50 | <.0001 |
| TRTPN (ATPTN) | | 1 | 3 | 1.1290 | 0.1391 | 5652 | 8.12 | <.0001 |
| TRTPN (ATPTN) | | 2 | 3 | 1.6932 | 0.1867 | 5654 | 9.07 | <.0001 |
| TRTPN (ATPTN) | | 3 | 3 | 0.9288 | 0.1866 | 5651 | 4.98 | <.0001 |
| TRTPN (ATPTN) | | 1 | 4 | 3.6173 | 0.1390 | 5651 | 26.03 | <.0001 |
| TRTPN (ATPTN) | | 2 | 4 | 4.7494 | 0.1869 | 5655 | 25.41 | <.0001 |
| TRTPN (ATPTN) | | 3 | 4 | 2.8978 | 0.1868 | 5651 | 15.51 | <.0001 |
| TRTPN (ATPTN) | | 1 | 5 | 1.2618 | 0.1387 | 5652 | 9.10 | <.0001 |
| TRTPN (ATPTN) | | 2 | 5 | 1.9783 | 0.1860 | 5652 | 10.63 | <.0001 |
| TRTPN (ATPTN) | | 3 | 5 | 0.9111 | 0.1866 | 5651 | 4.88 | <.0001 |
| TRTPN (ATPTN) | | 1 | 6 | 4.0292 | 0.1390 | 5653 | 28.99 | <.0001 |
| TRTPN (ATPTN) | | 2 | 6 | 4.8940 | 0.1861 | 5652 | 26.30 | <.0001 |
| TRTPN (ATPTN) | | 3 | 6 | 2.9201 | 0.1867 | 5651 | 15.64 | <.0001 |
| TRTPN (ATPTN) | | 1 | 7 | 2.7960 | 0.1392 | 5654 | 20.08 | <.0001 |
| TRTPN (ATPTN) | | 2 | 7 | 3.4588 | 0.1873 | 5655 | 18.47 | <.0001 |
| TRTPN (ATPTN) | | 3 | 7 | 1.8831 | 0.1871 | 5652 | 10.07 | <.0001 |
| TRTPN (ATPTN) | | 1 | 8 | 0.2813 | 0.1397 | 5654 | 2.01 | 0.0440 |
| TRTPN (ATPTN) | | 2 | 8 | 0.6376 | 0.1880 | 5657 | 3.39 | 0.0007 |
| TRTPN (ATPTN) | | 3 | 8 | 0.1064 | 0.1877 | 5653 | 0.57 | 0.5710 |
| TRTPN (ATPTN) | | 1 | 9 | 0 | | | | |
| TRTPN (ATPTN) | | 2 | 9 | 0 | | | | |
| TRTPN (ATPTN) | | 3 | 9 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 1 | -0.1375 | 0.1743 | 2641 | -0.79 | 0.4302 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 1 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 2 | -0.7606 | 0.1750 | 2671 | -4.35 | <.0001 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 2 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 3 | -0.5825 | 0.1749 | 2665 | -3.33 | 0.0009 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 3 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 4 | -0.4914 | 0.1752 | 2678 | -2.80 | 0.0051 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 4 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 5 | -0.6473 | 0.1749 | 2664 | -3.70 | 0.0002 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 5 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 6 | -0.7595 | 0.1751 | 2675 | -4.34 | <.0001 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 6 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 7 | -0.7914 | 0.1758 | 2705 | -4.50 | <.0001 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 7 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 8 | -0.3572 | 0.1766 | 2738 | -2.02 | 0.0432 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 8 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 9 | -0.2029 | 0.1744 | 2648 | -1.16 | 0.2449 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 9 | 0 | | | | |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-----------------|--------|--------|---------|--------|
| TRTPN | 2 | 716 | 39.78 | <.0001 |
| TRTPN (ATPTN) | 16 | 5652 | 8.63 | <.0001 |
| PREOAD2 (ATPTN) | 9 | 5392 | 5.07 | <.0001 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|---------------|-------------------------------------|------------------------|---------------|----------|----------------|------|---------|---------|
| TRTPN (ATPTN) | 1 | 1 | WORK.ANA_DATA | 5.5825 | 0.1153 | 2641 | 48.42 | <.0001 |
| TRTPN (ATPTN) | 2 | 1 | WORK.ANA_DATA | 5.8941 | 0.1637 | 2641 | 36.00 | <.0001 |
| TRTPN (ATPTN) | 3 | 1 | WORK.ANA_DATA | 7.1698 | 0.1633 | 2641 | 43.92 | <.0001 |
| TRTPN (ATPTN) | 1 | 2 | WORK.ANA_DATA | 9.1163 | 0.1155 | 2655 | 78.92 | <.0001 |
| TRTPN (ATPTN) | 2 | 2 | WORK.ANA_DATA | 9.9728 | 0.1650 | 2697 | 60.45 | <.0001 |
| TRTPN (ATPTN) | 3 | 2 | WORK.ANA_DATA | 10.3959 | 0.1638 | 2669 | 63.45 | <.0001 |
| TRTPN (ATPTN) | 1 | 3 | WORK.ANA_DATA | 6.5115 | 0.1158 | 2676 | 56.22 | <.0001 |
| TRTPN (ATPTN) | 2 | 3 | WORK.ANA_DATA | 7.2713 | 0.1647 | 2683 | 44.15 | <.0001 |
| TRTPN (ATPTN) | 3 | 3 | WORK.ANA_DATA | 7.9183 | 0.1633 | 2641 | 48.50 | <.0001 |
| TRTPN (ATPTN) | 1 | 4 | WORK.ANA_DATA | 9.0295 | 0.1157 | 2669 | 78.03 | <.0001 |
| TRTPN (ATPTN) | 2 | 4 | WORK.ANA_DATA | 10.3571 | 0.1650 | 2697 | 62.77 | <.0001 |
| TRTPN (ATPTN) | 3 | 4 | WORK.ANA_DATA | 9.9170 | 0.1636 | 2655 | 60.63 | <.0001 |
| TRTPN (ATPTN) | 1 | 5 | WORK.ANA_DATA | 6.6233 | 0.1156 | 2662 | 57.29 | <.0001 |
| TRTPN (ATPTN) | 2 | 5 | WORK.ANA_DATA | 7.5353 | 0.1641 | 2654 | 45.93 | <.0001 |
| TRTPN (ATPTN) | 3 | 5 | WORK.ANA_DATA | 7.8796 | 0.1633 | 2641 | 48.26 | <.0001 |
| TRTPN (ATPTN) | 1 | 6 | WORK.ANA_DATA | 9.3542 | 0.1159 | 2683 | 80.69 | <.0001 |
| TRTPN (ATPTN) | 2 | 6 | WORK.ANA_DATA | 10.4145 | 0.1641 | 2654 | 63.48 | <.0001 |
| TRTPN (ATPTN) | 3 | 6 | WORK.ANA_DATA | 9.8521 | 0.1633 | 2641 | 60.35 | <.0001 |
| TRTPN (ATPTN) | 1 | 7 | WORK.ANA_DATA | 8.1106 | 0.1163 | 2704 | 69.77 | <.0001 |
| TRTPN (ATPTN) | 2 | 7 | WORK.ANA_DATA | 8.9690 | 0.1653 | 2712 | 54.26 | <.0001 |
| TRTPN (ATPTN) | 3 | 7 | WORK.ANA_DATA | 8.8047 | 0.1636 | 2655 | 53.83 | <.0001 |
| TRTPN (ATPTN) | 1 | 8 | WORK.ANA_DATA | 5.7371 | 0.1167 | 2733 | 49.17 | <.0001 |
| TRTPN (ATPTN) | 2 | 8 | WORK.ANA_DATA | 6.2889 | 0.1659 | 2741 | 37.90 | <.0001 |
| TRTPN (ATPTN) | 3 | 8 | WORK.ANA_DATA | 7.1691 | 0.1644 | 2697 | 43.60 | <.0001 |
| TRTPN (ATPTN) | 1 | 9 | WORK.ANA_DATA | 5.5059 | 0.1155 | 2655 | 47.67 | <.0001 |
| TRTPN (ATPTN) | 2 | 9 | WORK.ANA_DATA | 5.7015 | 0.1637 | 2641 | 34.82 | <.0001 |
| TRTPN (ATPTN) | 3 | 9 | WORK.ANA_DATA | 7.1129 | 0.1638 | 2669 | 43.41 | <.0001 |

Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Alpha | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------|---------|---------|
| TRTPN (ATPTN) | 1 | 1 | 0.05 | 5.3565 | 5.8086 |
| TRTPN (ATPTN) | 2 | 1 | 0.05 | 5.5730 | 6.2151 |
| TRTPN (ATPTN) | 3 | 1 | 0.05 | 6.8497 | 7.4900 |
| TRTPN (ATPTN) | 1 | 2 | 0.05 | 8.8898 | 9.3428 |
| TRTPN (ATPTN) | 2 | 2 | 0.05 | 9.6493 | 10.2963 |
| TRTPN (ATPTN) | 3 | 2 | 0.05 | 10.0746 | 10.7172 |
| TRTPN (ATPTN) | 1 | 3 | 0.05 | 6.2844 | 6.7387 |
| TRTPN (ATPTN) | 2 | 3 | 0.05 | 6.9483 | 7.5942 |
| TRTPN (ATPTN) | 3 | 3 | 0.05 | 7.5982 | 8.2384 |
| TRTPN (ATPTN) | 1 | 4 | 0.05 | 8.8026 | 9.2564 |
| TRTPN (ATPTN) | 2 | 4 | 0.05 | 10.0335 | 10.6806 |
| TRTPN (ATPTN) | 3 | 4 | 0.05 | 9.5962 | 10.2377 |
| TRTPN (ATPTN) | 1 | 5 | 0.05 | 6.3966 | 6.8500 |
| TRTPN (ATPTN) | 2 | 5 | 0.05 | 7.2136 | 7.8571 |
| TRTPN (ATPTN) | 3 | 5 | 0.05 | 7.5594 | 8.1997 |
| TRTPN (ATPTN) | 1 | 6 | 0.05 | 9.1269 | 9.5815 |
| TRTPN (ATPTN) | 2 | 6 | 0.05 | 10.0928 | 10.7362 |
| TRTPN (ATPTN) | 3 | 6 | 0.05 | 9.5320 | 10.1722 |
| TRTPN (ATPTN) | 1 | 7 | 0.05 | 7.8827 | 8.3386 |
| TRTPN (ATPTN) | 2 | 7 | 0.05 | 8.6449 | 9.2931 |
| TRTPN (ATPTN) | 3 | 7 | 0.05 | 8.4840 | 9.1254 |
| TRTPN (ATPTN) | 1 | 8 | 0.05 | 5.5083 | 5.9660 |
| TRTPN (ATPTN) | 2 | 8 | 0.05 | 5.9636 | 6.6142 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Alpha | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------|--------|--------|
| TRTPN (ATPTN) | 3 | 8 | 0.05 | 6.8466 | 7.4915 |
| TRTPN (ATPTN) | 1 | 9 | 0.05 | 5.2795 | 5.7324 |
| TRTPN (ATPTN) | 2 | 9 | 0.05 | 5.3804 | 6.0225 |
| TRTPN (ATPTN) | 3 | 9 | 0.05 | 6.7916 | 7.4342 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 1 | 1 | 2 | 1 | WORK.ANA_DATA | -0.3115 | 0.2002 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 1 | WORK.ANA_DATA | -1.5873 | 0.1999 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 2 | WORK.ANA_DATA | -3.5338 | 0.1241 | 5652 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 2 | WORK.ANA_DATA | -4.3903 | 0.2013 | 2679 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 2 | WORK.ANA_DATA | -4.8133 | 0.2003 | 2660 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 3 | WORK.ANA_DATA | -0.9290 | 0.1244 | 5653 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 3 | WORK.ANA_DATA | -1.6887 | 0.2010 | 2669 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 3 | WORK.ANA_DATA | -2.3358 | 0.1999 | 2641 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 1 | 1 | 2 | 1 | -1.56 | 0.1199 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 1 | -7.94 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 2 | -28.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 2 | -21.81 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 2 | -24.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 3 | -7.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 3 | -8.40 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 3 | -11.69 | <.0001 | 0.05 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|
| TRTPN (ATPTN) | 1 | 1 | 2 | 1 | -0.7042 | 0.08110 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 1 | -1.9792 | -1.1954 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 2 | -3.7771 | -3.2904 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 2 | -4.7850 | -3.9956 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 2 | -5.2062 | -4.4205 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 3 | -1.1729 | -0.6851 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 3 | -2.0829 | -1.2945 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 3 | -2.7277 | -1.9439 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 1 | 1 | 1 | 4 | WORK.ANA_DATA | -3.4470 | 0.1243 | 5653 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 4 | WORK.ANA_DATA | -4.7745 | 0.2013 | 2679 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 4 | WORK.ANA_DATA | -4.3344 | 0.2001 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 5 | WORK.ANA_DATA | -1.0408 | 0.1242 | 5652 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 5 | WORK.ANA_DATA | -1.9528 | 0.2005 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 5 | WORK.ANA_DATA | -2.2970 | 0.1999 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 6 | WORK.ANA_DATA | -3.7717 | 0.1245 | 5653 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 6 | WORK.ANA_DATA | -4.8320 | 0.2005 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 6 | WORK.ANA_DATA | -4.2696 | 0.1999 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 7 | WORK.ANA_DATA | -2.5281 | 0.1248 | 5654 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 7 | WORK.ANA_DATA | -3.3864 | 0.2015 | 2688 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 7 | WORK.ANA_DATA | -3.2222 | 0.2001 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 8 | WORK.ANA_DATA | -0.1546 | 0.1252 | 5656 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 8 | WORK.ANA_DATA | -0.7064 | 0.2020 | 2708 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 8 | WORK.ANA_DATA | -1.5866 | 0.2008 | 2679 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 9 | WORK.ANA_DATA | 0.07658 | 0.1241 | 5650 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 9 | WORK.ANA_DATA | -0.1189 | 0.2002 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 9 | WORK.ANA_DATA | -1.5304 | 0.2003 | 2660 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 1 | WORK.ANA_DATA | -1.2758 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 2 | WORK.ANA_DATA | -3.2222 | 0.2004 | 2645 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 2 | WORK.ANA_DATA | -4.0788 | 0.1772 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 2 | WORK.ANA_DATA | -4.5018 | 0.2316 | 2655 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 3 | WORK.ANA_DATA | -0.6175 | 0.2006 | 2652 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 3 | WORK.ANA_DATA | -1.3772 | 0.1769 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 3 | WORK.ANA_DATA | -2.0242 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 4 | WORK.ANA_DATA | -3.1354 | 0.2005 | 2650 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 4 | WORK.ANA_DATA | -4.4630 | 0.1772 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 4 | WORK.ANA_DATA | -4.0229 | 0.2314 | 2648 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 5 | WORK.ANA_DATA | -0.7292 | 0.2004 | 2648 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 5 | WORK.ANA_DATA | -1.6413 | 0.1763 | 5653 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 5 | WORK.ANA_DATA | -1.9855 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 6 | WORK.ANA_DATA | -3.4602 | 0.2006 | 2655 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 6 | WORK.ANA_DATA | -4.5205 | 0.1763 | 5653 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 6 | WORK.ANA_DATA | -3.9580 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 7 | WORK.ANA_DATA | -2.2166 | 0.2008 | 2662 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 7 | WORK.ANA_DATA | -3.0749 | 0.1774 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 7 | WORK.ANA_DATA | -2.9106 | 0.2314 | 2648 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 8 | WORK.ANA_DATA | 0.1569 | 0.2011 | 2672 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 8 | WORK.ANA_DATA | -0.3948 | 0.1780 | 5658 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 8 | WORK.ANA_DATA | -1.2750 | 0.2320 | 2669 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 9 | WORK.ANA_DATA | 0.3881 | 0.2004 | 2646 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 9 | WORK.ANA_DATA | 0.1926 | 0.1760 | 5649 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 9 | WORK.ANA_DATA | -1.2188 | 0.2316 | 2655 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 2 | WORK.ANA_DATA | -1.9465 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 2 | WORK.ANA_DATA | -2.8030 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 2 | WORK.ANA_DATA | -3.2260 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 3 | WORK.ANA_DATA | 0.6583 | 0.2002 | 2653 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 3 | WORK.ANA_DATA | -0.1014 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 3 | WORK.ANA_DATA | -0.7485 | 0.1755 | 5649 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 4 | WORK.ANA_DATA | -1.8597 | 0.2001 | 2650 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 4 | WORK.ANA_DATA | -3.1872 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 4 | WORK.ANA_DATA | -2.7471 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 5 | WORK.ANA_DATA | 0.5465 | 0.2001 | 2648 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 5 | WORK.ANA_DATA | -0.3655 | 0.2315 | 2648 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 5 | WORK.ANA_DATA | -0.7097 | 0.1755 | 5649 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 6 | WORK.ANA_DATA | -2.1844 | 0.2002 | 2655 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 6 | WORK.ANA_DATA | -3.2447 | 0.2315 | 2648 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 6 | WORK.ANA_DATA | -2.6823 | 0.1755 | 5649 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 7 | WORK.ANA_DATA | -0.9408 | 0.2004 | 2662 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 1 | 1 | 1 | 4 | -27.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 4 | -23.72 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 4 | -21.66 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 5 | -8.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 5 | -9.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 5 | -11.49 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 6 | -30.29 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 6 | -24.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 6 | -21.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 7 | -20.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 7 | -16.80 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 7 | -16.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 8 | -1.23 | 0.2170 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 8 | -3.50 | 0.0005 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 8 | -7.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 9 | 0.62 | 0.5372 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 9 | -0.59 | 0.5526 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 9 | -7.64 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 1 | -5.52 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 2 | -16.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 2 | -23.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 2 | -19.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 3 | -3.08 | 0.0021 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 3 | -7.79 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 3 | -8.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 4 | -15.64 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 4 | -25.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 4 | -17.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 5 | -3.64 | 0.0003 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 5 | -9.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 5 | -8.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 6 | -17.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 6 | -25.64 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 6 | -17.12 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 7 | -11.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 7 | -17.33 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 7 | -12.58 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 8 | 0.78 | 0.4351 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 8 | -2.22 | 0.0266 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 8 | -5.49 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 9 | 1.94 | 0.0528 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 9 | 1.09 | 0.2738 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 9 | -5.26 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 2 | -9.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 2 | -12.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 2 | -18.33 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 3 | 3.29 | 0.0010 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 3 | -0.44 | 0.6619 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 3 | -4.27 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 4 | -9.29 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 4 | -13.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 4 | -15.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 5 | 2.73 | 0.0063 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 5 | -1.58 | 0.1144 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 5 | -4.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 6 | -10.91 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 6 | -14.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 6 | -15.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 7 | -4.69 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 1 | 1 | 1 | 4 | -3.6907 | -3.2032 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 4 | -5.1692 | -4.3798 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 4 | -4.7268 | -3.9421 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 5 | -1.2843 | -0.7972 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 5 | -2.3460 | -1.5596 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 5 | -2.6889 | -1.9051 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 6 | -4.0158 | -3.5276 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 6 | -5.2252 | -4.4388 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 6 | -4.6615 | -3.8777 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 7 | -2.7728 | -2.2834 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 7 | -3.7816 | -2.9913 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 7 | -3.6145 | -2.8298 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 8 | -0.4001 | 0.09088 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 8 | -1.1025 | -0.3102 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 8 | -1.9804 | -1.1928 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 9 | -0.1667 | 0.3199 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 9 | -0.5116 | 0.2737 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 9 | -1.9232 | -1.1375 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 1 | -1.7291 | -0.8224 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 2 | -3.6151 | -2.8293 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 2 | -4.4261 | -3.7315 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 2 | -4.9560 | -4.0476 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 3 | -1.0107 | -0.2242 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 3 | -1.7239 | -1.0304 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 3 | -2.4776 | -1.5708 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 4 | -3.5286 | -2.7423 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 4 | -4.8103 | -4.1157 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 4 | -4.4767 | -3.5691 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 5 | -1.1223 | -0.3362 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 5 | -1.9869 | -1.2957 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 5 | -2.4389 | -1.5321 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 6 | -3.8535 | -3.0668 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 6 | -4.8661 | -4.1748 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 6 | -4.4114 | -3.5047 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 7 | -2.6103 | -1.8228 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 7 | -3.4227 | -2.7271 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 7 | -3.3644 | -2.4568 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 8 | -0.2373 | 0.5512 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 8 | -0.7438 | -0.04583 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 8 | -1.7300 | -0.8200 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 9 | -0.00476 | 0.7810 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 9 | -0.1524 | 0.5376 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 9 | -1.6730 | -0.7646 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 2 | -2.3386 | -1.5543 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 2 | -3.2581 | -2.3479 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 2 | -3.5711 | -2.8810 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 3 | 0.2658 | 1.0508 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 3 | -0.5562 | 0.3533 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 3 | -1.0925 | -0.4044 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 4 | -2.2521 | -1.4673 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 4 | -3.6424 | -2.7321 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 4 | -3.0917 | -2.4026 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 5 | 0.1542 | 0.9388 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 5 | -0.8194 | 0.08834 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 5 | -1.0538 | -0.3657 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 6 | -2.5770 | -1.7918 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 6 | -3.6986 | -2.7908 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 6 | -3.0263 | -2.3383 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 7 | -1.3338 | -0.5478 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 1 | 2 | 7 | WORK.ANA_DATA | -1.7991 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 7 | WORK.ANA_DATA | -1.6349 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 8 | WORK.ANA_DATA | 1.4327 | 0.2007 | 2672 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 8 | WORK.ANA_DATA | 0.8809 | 0.2328 | 2691 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 8 | WORK.ANA_DATA | 0.000731 | 0.1766 | 5651 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 9 | WORK.ANA_DATA | 1.6639 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 9 | WORK.ANA_DATA | 1.4684 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 9 | WORK.ANA_DATA | 0.05695 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 2 | WORK.ANA_DATA | -0.8566 | 0.2014 | 2683 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 2 | WORK.ANA_DATA | -1.2796 | 0.2005 | 2664 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 3 | WORK.ANA_DATA | 2.6048 | 0.1246 | 5650 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 3 | WORK.ANA_DATA | 1.8450 | 0.2012 | 2673 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 3 | WORK.ANA_DATA | 1.1980 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 4 | WORK.ANA_DATA | 0.08679 | 0.1245 | 5650 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 4 | WORK.ANA_DATA | -1.2408 | 0.2014 | 2683 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 4 | WORK.ANA_DATA | -0.8007 | 0.2002 | 2655 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 5 | WORK.ANA_DATA | 2.4930 | 0.1244 | 5651 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 5 | WORK.ANA_DATA | 1.5809 | 0.2007 | 2654 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 5 | WORK.ANA_DATA | 1.2367 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 6 | WORK.ANA_DATA | -0.2379 | 0.1247 | 5652 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 6 | WORK.ANA_DATA | -1.2982 | 0.2007 | 2654 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 6 | WORK.ANA_DATA | -0.7358 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 7 | WORK.ANA_DATA | 1.0056 | 0.1250 | 5653 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 7 | WORK.ANA_DATA | 0.1473 | 0.2017 | 2693 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 7 | WORK.ANA_DATA | 0.3116 | 0.2002 | 2655 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 8 | WORK.ANA_DATA | 3.3791 | 0.1254 | 5653 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 8 | WORK.ANA_DATA | 2.8274 | 0.2022 | 2712 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 8 | WORK.ANA_DATA | 1.9472 | 0.2010 | 2683 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 9 | WORK.ANA_DATA | 3.6103 | 0.1243 | 5651 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 9 | WORK.ANA_DATA | 3.4148 | 0.2004 | 2645 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 9 | WORK.ANA_DATA | 2.0034 | 0.2005 | 2664 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 2 | WORK.ANA_DATA | -0.4230 | 0.2325 | 2683 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 3 | WORK.ANA_DATA | 3.4613 | 0.2016 | 2690 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 3 | WORK.ANA_DATA | 2.7016 | 0.1778 | 5652 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 3 | WORK.ANA_DATA | 2.0546 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 4 | WORK.ANA_DATA | 0.9433 | 0.2015 | 2688 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 4 | WORK.ANA_DATA | -0.3842 | 0.1781 | 5652 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 4 | WORK.ANA_DATA | 0.05589 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 5 | WORK.ANA_DATA | 3.3495 | 0.2015 | 2685 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 5 | WORK.ANA_DATA | 2.4375 | 0.1773 | 5651 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 5 | WORK.ANA_DATA | 2.0933 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 6 | WORK.ANA_DATA | 0.6186 | 0.2016 | 2692 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 6 | WORK.ANA_DATA | -0.4417 | 0.1773 | 5651 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 6 | WORK.ANA_DATA | 0.1207 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 7 | WORK.ANA_DATA | 1.8622 | 0.2018 | 2699 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 7 | WORK.ANA_DATA | 1.0039 | 0.1784 | 5653 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 7 | WORK.ANA_DATA | 1.1682 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 8 | WORK.ANA_DATA | 4.2357 | 0.2021 | 2709 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 8 | WORK.ANA_DATA | 3.6840 | 0.1790 | 5654 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 8 | WORK.ANA_DATA | 2.8037 | 0.2329 | 2697 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 9 | WORK.ANA_DATA | 4.4669 | 0.2014 | 2683 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 9 | WORK.ANA_DATA | 4.2714 | 0.1772 | 5656 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 9 | WORK.ANA_DATA | 2.8600 | 0.2325 | 2683 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 3 | WORK.ANA_DATA | 3.8843 | 0.2007 | 2671 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 3 | WORK.ANA_DATA | 3.1246 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 3 | WORK.ANA_DATA | 2.4776 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 4 | WORK.ANA_DATA | 1.3664 | 0.2006 | 2669 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 4 | WORK.ANA_DATA | 0.03882 | 0.2325 | 2683 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 4 | WORK.ANA_DATA | 0.4789 | 0.1763 | 5651 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 1 | 2 | 7 | -7.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 7 | -9.30 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 8 | 7.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 8 | 3.78 | 0.0002 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 8 | 0.00 | 0.9967 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 9 | 8.32 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 9 | 6.35 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 9 | 0.32 | 0.7463 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 2 | -4.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 2 | -6.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 3 | 20.91 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 3 | 9.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 3 | 5.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 4 | 0.70 | 0.4856 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 4 | -6.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 4 | -4.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 5 | 20.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 5 | 7.88 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 5 | 6.18 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 6 | -1.91 | 0.0564 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 6 | -6.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 6 | -3.68 | 0.0002 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 7 | 8.05 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 7 | 0.73 | 0.4651 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 7 | 1.56 | 0.1198 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 8 | 26.96 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 8 | 13.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 8 | 9.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 9 | 29.05 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 9 | 17.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 9 | 9.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 2 | -1.82 | 0.0690 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 3 | 17.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 3 | 15.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 3 | 8.85 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 4 | 4.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 4 | -2.16 | 0.0310 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 4 | 0.24 | 0.8099 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 5 | 16.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 5 | 13.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 5 | 9.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 6 | 3.07 | 0.0022 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 6 | -2.49 | 0.0128 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 6 | 0.52 | 0.6030 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 7 | 9.23 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 7 | 5.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 7 | 5.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 8 | 20.96 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 8 | 20.58 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 8 | 12.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 9 | 22.18 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 9 | 24.11 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 9 | 12.30 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 3 | 19.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 3 | 13.45 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 3 | 14.07 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 4 | 6.81 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 4 | 0.17 | 0.8674 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 4 | 2.72 | 0.0066 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 1 | 2 | 7 | -2.2547 | -1.3436 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 7 | -1.9794 | -1.2903 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 8 | 1.0392 | 1.8262 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 8 | 0.4245 | 1.3374 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 8 | -0.3454 | 0.3469 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 9 | 1.2717 | 2.0560 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 9 | 1.0150 | 1.9217 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 9 | -0.2881 | 0.4020 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 2 | -1.2515 | -0.4616 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 2 | -1.6727 | -0.8865 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 3 | 2.3606 | 2.8489 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 3 | 1.4506 | 2.2395 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 3 | 0.8058 | 1.5902 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 4 | -0.1572 | 0.3308 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 4 | -1.6357 | -0.8458 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 4 | -1.1933 | -0.4080 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 5 | 2.2491 | 2.7368 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 5 | 1.1875 | 1.9744 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 5 | 0.8446 | 1.6289 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 6 | -0.4824 | 0.006482 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 6 | -1.6917 | -0.9048 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 6 | -1.1280 | -0.3437 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 7 | 0.7606 | 1.2507 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 7 | -0.2481 | 0.5427 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 7 | -0.08103 | 0.7042 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 8 | 3.1334 | 3.6249 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 8 | 2.4310 | 3.2238 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 8 | 1.5531 | 2.3412 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 9 | 3.3667 | 3.8540 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 9 | 3.0219 | 3.8077 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 9 | 1.6103 | 2.3965 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 2 | -0.8790 | 0.03292 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 3 | 3.0660 | 3.8566 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 3 | 2.3530 | 3.0502 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 3 | 1.5994 | 2.5097 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 4 | 0.5482 | 1.3385 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 4 | -0.7334 | -0.03505 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 4 | -0.3996 | 0.5114 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 5 | 2.9545 | 3.7446 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 5 | 2.0899 | 2.7851 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 5 | 1.6381 | 2.5484 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 6 | 0.2232 | 1.0140 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 6 | -0.7893 | -0.09404 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 6 | -0.3344 | 0.5759 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 7 | 1.4664 | 2.2580 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 7 | 0.6541 | 1.3536 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 7 | 0.7126 | 1.6237 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 8 | 3.8395 | 4.6319 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 8 | 3.3331 | 4.0348 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 8 | 2.3470 | 3.2605 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 9 | 4.0720 | 4.8618 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 9 | 3.9241 | 4.6187 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 9 | 2.4040 | 3.3159 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 3 | 3.4909 | 4.2778 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 3 | 2.6691 | 3.5801 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 3 | 2.1325 | 2.8227 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 4 | 0.9730 | 1.7597 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 4 | -0.4171 | 0.4948 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 4 | 0.1333 | 0.8245 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 2 | 1 | 5 | WORK.ANA_DATA | 3.7726 | 0.2005 | 2667 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 5 | WORK.ANA_DATA | 2.8605 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 5 | WORK.ANA_DATA | 2.5163 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 6 | WORK.ANA_DATA | 1.0416 | 0.2007 | 2674 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 6 | WORK.ANA_DATA | -0.01865 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 6 | WORK.ANA_DATA | 0.5438 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 7 | WORK.ANA_DATA | 2.2852 | 0.2009 | 2681 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 7 | WORK.ANA_DATA | 1.4269 | 0.2327 | 2690 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 7 | WORK.ANA_DATA | 1.5912 | 0.1763 | 5651 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 8 | WORK.ANA_DATA | 4.6587 | 0.2012 | 2690 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 8 | WORK.ANA_DATA | 4.1070 | 0.2332 | 2705 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 8 | WORK.ANA_DATA | 3.2268 | 0.1771 | 5652 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 9 | WORK.ANA_DATA | 4.8899 | 0.2005 | 2664 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 9 | WORK.ANA_DATA | 4.6944 | 0.2316 | 2655 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 9 | WORK.ANA_DATA | 3.2830 | 0.1766 | 5651 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 3 | WORK.ANA_DATA | -0.7597 | 0.2013 | 2680 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 3 | WORK.ANA_DATA | -1.4068 | 0.2002 | 2653 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 4 | WORK.ANA_DATA | -2.5180 | 0.1247 | 5650 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 4 | WORK.ANA_DATA | -3.8455 | 0.2016 | 2690 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 4 | WORK.ANA_DATA | -3.4054 | 0.2004 | 2662 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 5 | WORK.ANA_DATA | -0.1118 | 0.1247 | 5651 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 5 | WORK.ANA_DATA | -1.0238 | 0.2008 | 2661 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 5 | WORK.ANA_DATA | -1.3680 | 0.2002 | 2653 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 6 | WORK.ANA_DATA | -2.8427 | 0.1250 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 6 | WORK.ANA_DATA | -3.9030 | 0.2008 | 2661 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 6 | WORK.ANA_DATA | -3.3406 | 0.2002 | 2653 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 7 | WORK.ANA_DATA | -1.5991 | 0.1252 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 7 | WORK.ANA_DATA | -2.4574 | 0.2018 | 2700 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 7 | WORK.ANA_DATA | -2.2932 | 0.2004 | 2662 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 8 | WORK.ANA_DATA | 0.7744 | 0.1256 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 8 | WORK.ANA_DATA | 0.2226 | 0.2023 | 2719 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 8 | WORK.ANA_DATA | -0.6576 | 0.2011 | 2690 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 9 | WORK.ANA_DATA | 1.0056 | 0.1246 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 9 | WORK.ANA_DATA | 0.8101 | 0.2006 | 2652 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 9 | WORK.ANA_DATA | -0.6013 | 0.2007 | 2671 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 3 | WORK.ANA_DATA | -0.6470 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 4 | WORK.ANA_DATA | -1.7582 | 0.2013 | 2678 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 4 | WORK.ANA_DATA | -3.0858 | 0.1778 | 5650 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 4 | WORK.ANA_DATA | -2.6457 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 5 | WORK.ANA_DATA | 0.6480 | 0.2012 | 2676 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 5 | WORK.ANA_DATA | -0.2641 | 0.1771 | 5651 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 5 | WORK.ANA_DATA | -0.6083 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 6 | WORK.ANA_DATA | -2.0830 | 0.2014 | 2683 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 6 | WORK.ANA_DATA | -3.1433 | 0.1771 | 5651 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 6 | WORK.ANA_DATA | -2.5809 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 7 | WORK.ANA_DATA | -0.8394 | 0.2016 | 2690 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 7 | WORK.ANA_DATA | -1.6977 | 0.1781 | 5652 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 7 | WORK.ANA_DATA | -1.5334 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 8 | WORK.ANA_DATA | 1.5341 | 0.2018 | 2699 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 8 | WORK.ANA_DATA | 0.9824 | 0.1786 | 5651 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 8 | WORK.ANA_DATA | 0.1022 | 0.2327 | 2690 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 9 | WORK.ANA_DATA | 1.7653 | 0.2012 | 2673 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 9 | WORK.ANA_DATA | 1.5698 | 0.1769 | 5656 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 9 | WORK.ANA_DATA | 0.1584 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 4 | WORK.ANA_DATA | -1.1112 | 0.2001 | 2650 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 4 | WORK.ANA_DATA | -2.4388 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 4 | WORK.ANA_DATA | -1.9987 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 5 | WORK.ANA_DATA | 1.2950 | 0.2001 | 2648 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 5 | WORK.ANA_DATA | 0.3829 | 0.2315 | 2648 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 2 | 1 | 5 | 18.81 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 5 | 12.34 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 5 | 14.29 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 6 | 5.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 6 | -0.08 | 0.9359 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 6 | 3.09 | 0.0020 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 7 | 11.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 7 | 6.13 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 7 | 9.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 8 | 23.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 8 | 17.61 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 8 | 18.22 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 9 | 24.39 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 9 | 20.27 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 9 | 18.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 3 | -3.77 | 0.0002 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 3 | -7.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 4 | -20.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 4 | -19.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 4 | -16.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 5 | -0.90 | 0.3700 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 5 | -5.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 5 | -6.83 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 6 | -22.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 6 | -19.43 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 6 | -16.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 7 | -12.77 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 7 | -12.18 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 7 | -11.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 8 | 6.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 8 | 1.10 | 0.2713 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 8 | -3.27 | 0.0011 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 9 | 8.07 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 9 | 4.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 9 | -3.00 | 0.0028 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 3 | -2.79 | 0.0053 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 4 | -8.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 4 | -17.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 4 | -11.40 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 5 | 3.22 | 0.0013 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 5 | -1.49 | 0.1359 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 5 | -2.62 | 0.0088 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 6 | -10.34 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 6 | -17.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 6 | -11.13 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 7 | -4.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 7 | -9.53 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 7 | -6.61 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 8 | 7.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 8 | 5.50 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 8 | 0.44 | 0.6607 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 9 | 8.78 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 9 | 8.87 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 9 | 0.68 | 0.4955 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 4 | -5.55 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 4 | -10.51 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 4 | -11.37 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 5 | 6.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 5 | 1.65 | 0.0982 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|---------|
| TRTPN (ATPTN) | 3 | 2 | 1 | 5 | 3.3794 | 4.1658 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 5 | 2.4059 | 3.3152 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 5 | 2.1712 | 2.8614 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 6 | 0.6481 | 1.4352 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 6 | -0.4733 | 0.4360 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 6 | 0.1987 | 0.8889 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 7 | 1.8913 | 2.6792 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 7 | 0.9705 | 1.8833 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 7 | 1.2456 | 1.9368 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 8 | 4.2643 | 5.0532 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 8 | 3.6498 | 4.5642 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 8 | 2.8795 | 3.5740 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 9 | 4.4968 | 5.2830 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 9 | 4.2402 | 5.1486 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 9 | 2.9368 | 3.6292 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 3 | -1.1545 | -0.3649 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 3 | -1.7993 | -1.0142 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 4 | -2.7625 | -2.2734 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 4 | -4.2408 | -3.4502 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 4 | -3.7984 | -3.0124 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 5 | -0.3562 | 0.1326 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 5 | -1.4176 | -0.6300 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 5 | -1.7606 | -0.9755 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 6 | -3.0877 | -2.5977 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 6 | -4.2968 | -3.5092 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 6 | -3.7331 | -2.9481 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 7 | -1.8446 | -1.3536 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 7 | -2.8532 | -2.0617 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 7 | -2.6861 | -1.9002 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 8 | 0.5281 | 1.0207 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 8 | -0.1741 | 0.6194 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 8 | -1.0520 | -0.2632 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 9 | 0.7613 | 1.2498 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 9 | 0.4168 | 1.2033 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 9 | -0.9948 | -0.2079 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 3 | -1.1017 | -0.1923 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 4 | -2.1529 | -1.3636 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 4 | -3.4343 | -2.7373 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 4 | -3.1008 | -2.1906 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 5 | 0.2534 | 1.0425 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 5 | -0.6112 | 0.08300 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 5 | -1.0630 | -0.1536 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 6 | -2.4779 | -1.6881 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 6 | -3.4904 | -2.7962 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 6 | -3.0356 | -2.1261 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 7 | -1.2347 | -0.4441 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 7 | -2.0469 | -1.3486 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 7 | -1.9886 | -1.0783 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 8 | 1.1383 | 1.9299 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 8 | 0.6322 | 1.3325 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 8 | -0.3542 | 0.5585 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 9 | 1.3709 | 2.1597 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 9 | 1.2230 | 1.9165 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 9 | -0.2972 | 0.6139 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 4 | -1.5036 | -0.7188 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 4 | -2.8939 | -1.9836 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 4 | -2.3432 | -1.6541 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 5 | 0.9027 | 1.6873 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 5 | -0.07093 | 0.8368 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 3 | 3 | 5 | WORK.ANA_DATA | 0.03871 | 0.1755 | 5649 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 6 | WORK.ANA_DATA | -1.4359 | 0.2002 | 2655 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 6 | WORK.ANA_DATA | -2.4962 | 0.2315 | 2648 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 6 | WORK.ANA_DATA | -1.9338 | 0.1755 | 5649 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 7 | WORK.ANA_DATA | -0.1924 | 0.2004 | 2662 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 7 | WORK.ANA_DATA | -1.0507 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 7 | WORK.ANA_DATA | -0.8864 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 8 | WORK.ANA_DATA | 2.1811 | 0.2007 | 2672 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 8 | WORK.ANA_DATA | 1.6294 | 0.2328 | 2691 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 8 | WORK.ANA_DATA | 0.7492 | 0.1766 | 5651 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 9 | WORK.ANA_DATA | 2.4123 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 9 | WORK.ANA_DATA | 2.2168 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 9 | WORK.ANA_DATA | 0.8054 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 4 | WORK.ANA_DATA | -1.3276 | 0.2015 | 2688 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 4 | WORK.ANA_DATA | -0.8875 | 0.2004 | 2659 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 5 | WORK.ANA_DATA | 2.4062 | 0.1246 | 5652 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 5 | WORK.ANA_DATA | 1.4941 | 0.2008 | 2659 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 5 | WORK.ANA_DATA | 1.1499 | 0.2001 | 2650 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 6 | WORK.ANA_DATA | -0.3247 | 0.1249 | 5652 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 6 | WORK.ANA_DATA | -1.3850 | 0.2008 | 2659 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 6 | WORK.ANA_DATA | -0.8226 | 0.2001 | 2650 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 7 | WORK.ANA_DATA | 0.9189 | 0.1252 | 5654 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 7 | WORK.ANA_DATA | 0.06053 | 0.2018 | 2697 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 7 | WORK.ANA_DATA | 0.2248 | 0.2004 | 2660 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 8 | WORK.ANA_DATA | 3.2924 | 0.1255 | 5653 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 8 | WORK.ANA_DATA | 2.7406 | 0.2023 | 2717 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 8 | WORK.ANA_DATA | 1.8604 | 0.2011 | 2688 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 9 | WORK.ANA_DATA | 3.5235 | 0.1245 | 5652 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 9 | WORK.ANA_DATA | 3.3280 | 0.2005 | 2650 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 9 | WORK.ANA_DATA | 1.9166 | 0.2006 | 2669 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 4 | WORK.ANA_DATA | 0.4401 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 5 | WORK.ANA_DATA | 3.7338 | 0.2015 | 2685 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 5 | WORK.ANA_DATA | 2.8217 | 0.1773 | 5652 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 5 | WORK.ANA_DATA | 2.4775 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 6 | WORK.ANA_DATA | 1.0028 | 0.2017 | 2692 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 6 | WORK.ANA_DATA | -0.05746 | 0.1773 | 5652 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 6 | WORK.ANA_DATA | 0.5049 | 0.2321 | 2669 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 7 | WORK.ANA_DATA | 2.2464 | 0.2018 | 2699 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 7 | WORK.ANA_DATA | 1.3881 | 0.1784 | 5653 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 7 | WORK.ANA_DATA | 1.5524 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 8 | WORK.ANA_DATA | 4.6199 | 0.2021 | 2709 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 8 | WORK.ANA_DATA | 4.0682 | 0.1789 | 5652 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 8 | WORK.ANA_DATA | 3.1880 | 0.2329 | 2697 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 9 | WORK.ANA_DATA | 4.8511 | 0.2014 | 2683 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 9 | WORK.ANA_DATA | 4.6556 | 0.1772 | 5656 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 9 | WORK.ANA_DATA | 3.2442 | 0.2325 | 2683 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 5 | WORK.ANA_DATA | 3.2936 | 0.2003 | 2657 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 5 | WORK.ANA_DATA | 2.3816 | 0.2317 | 2655 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 5 | WORK.ANA_DATA | 2.0374 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 6 | WORK.ANA_DATA | 0.5627 | 0.2005 | 2664 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 6 | WORK.ANA_DATA | -0.4976 | 0.2317 | 2655 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 6 | WORK.ANA_DATA | 0.06484 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 7 | WORK.ANA_DATA | 1.8063 | 0.2007 | 2671 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 7 | WORK.ANA_DATA | 0.9480 | 0.2325 | 2683 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 7 | WORK.ANA_DATA | 1.1123 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 8 | WORK.ANA_DATA | 4.1798 | 0.2009 | 2681 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 8 | WORK.ANA_DATA | 3.6281 | 0.2330 | 2698 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 8 | WORK.ANA_DATA | 2.7479 | 0.1769 | 5652 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 9 | WORK.ANA_DATA | 4.4110 | 0.2002 | 2655 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 3 | 3 | 5 | 0.22 | 0.8254 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 6 | -7.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 6 | -10.78 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 6 | -11.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 7 | -0.96 | 0.3373 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 7 | -4.52 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 7 | -5.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 8 | 10.87 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 8 | 7.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 8 | 4.24 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 9 | 12.06 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 9 | 9.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 9 | 4.58 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 4 | -6.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 4 | -4.43 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 5 | 19.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 5 | 7.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 5 | 5.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 6 | -2.60 | 0.0093 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 6 | -6.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 6 | -4.11 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 7 | 7.34 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 7 | 0.30 | 0.7642 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 7 | 1.12 | 0.2619 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 8 | 26.23 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 8 | 13.55 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 8 | 9.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 9 | 28.30 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 9 | 16.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 9 | 9.55 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 4 | 1.89 | 0.0583 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 5 | 18.53 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 5 | 15.91 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 5 | 10.67 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 6 | 4.97 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 6 | -0.32 | 0.7459 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 6 | 2.18 | 0.0297 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 7 | 11.13 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 7 | 7.78 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 7 | 6.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 8 | 22.86 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 8 | 22.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 8 | 13.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 9 | 24.09 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 9 | 26.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 9 | 13.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 5 | 16.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 5 | 10.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 5 | 11.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 6 | 2.81 | 0.0050 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 6 | -2.15 | 0.0318 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 6 | 0.37 | 0.7122 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 7 | 9.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 7 | 4.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 7 | 6.32 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 8 | 20.80 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 8 | 15.57 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 8 | 15.54 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 9 | 22.03 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 3 | 3 | 5 | -0.3053 | 0.3827 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 6 | -1.8286 | -1.0433 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 6 | -2.9501 | -2.0424 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 6 | -2.2778 | -1.5898 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 7 | -0.5854 | 0.2006 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 7 | -1.5062 | -0.5951 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 7 | -1.2310 | -0.5419 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 8 | 1.7876 | 2.5746 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 8 | 1.1730 | 2.0858 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 8 | 0.4030 | 1.0954 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 9 | 2.0202 | 2.8045 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 9 | 1.7634 | 2.6702 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 9 | 0.4603 | 1.1505 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 4 | -1.7227 | -0.9324 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 4 | -1.2803 | -0.4946 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 5 | 2.1620 | 2.6504 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 5 | 1.1005 | 1.8878 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 5 | 0.7575 | 1.5423 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 6 | -0.5695 | -0.07997 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 6 | -1.7787 | -0.9913 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 6 | -1.2150 | -0.4302 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 7 | 0.6735 | 1.1642 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 7 | -0.3351 | 0.4562 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 7 | -0.1681 | 0.6177 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 8 | 3.0463 | 3.5384 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 8 | 2.3440 | 3.1373 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 8 | 1.4661 | 2.2547 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 9 | 3.2795 | 3.7676 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 9 | 2.9349 | 3.7212 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 9 | 1.5233 | 2.3100 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 4 | -0.01544 | 0.8957 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 5 | 3.3387 | 4.1288 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 5 | 2.4741 | 3.1694 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 5 | 2.0223 | 2.9326 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 6 | 0.6074 | 1.3982 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 6 | -0.4051 | 0.2902 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 6 | 0.04980 | 0.9601 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 7 | 1.8506 | 2.6422 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 7 | 1.0384 | 1.7378 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 7 | 1.0968 | 2.0079 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 8 | 4.2237 | 5.0162 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 8 | 3.7175 | 4.4189 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 8 | 2.7312 | 3.6447 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 9 | 4.4562 | 5.2460 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 9 | 4.3083 | 5.0029 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 9 | 2.7882 | 3.7001 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 5 | 2.9009 | 3.6864 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 5 | 1.9273 | 2.8359 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 5 | 1.6928 | 2.3819 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 6 | 0.1696 | 0.9558 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 6 | -0.9518 | -0.04331 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 6 | -0.2797 | 0.4094 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 7 | 1.4128 | 2.1998 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 7 | 0.4920 | 1.4039 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 7 | 0.7672 | 1.4573 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 8 | 3.7858 | 4.5738 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 8 | 3.1712 | 4.0849 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 8 | 2.4011 | 3.0946 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 9 | 4.0184 | 4.8036 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 4 | 2 | 9 | WORK.ANA_DATA | 4.2155 | 0.2314 | 2648 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 9 | WORK.ANA_DATA | 2.8041 | 0.1763 | 5651 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 5 | WORK.ANA_DATA | -0.9120 | 0.2007 | 2657 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 5 | WORK.ANA_DATA | -1.2563 | 0.2001 | 2648 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 6 | WORK.ANA_DATA | -2.7309 | 0.1247 | 5651 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 6 | WORK.ANA_DATA | -3.7912 | 0.2007 | 2657 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 6 | WORK.ANA_DATA | -3.2288 | 0.2001 | 2648 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 7 | WORK.ANA_DATA | -1.4873 | 0.1250 | 5651 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 7 | WORK.ANA_DATA | -2.3457 | 0.2017 | 2695 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 7 | WORK.ANA_DATA | -2.1814 | 0.2003 | 2657 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 8 | WORK.ANA_DATA | 0.8862 | 0.1254 | 5653 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 8 | WORK.ANA_DATA | 0.3344 | 0.2022 | 2715 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 8 | WORK.ANA_DATA | -0.5458 | 0.2010 | 2685 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 9 | WORK.ANA_DATA | 1.1174 | 0.1244 | 5654 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 9 | WORK.ANA_DATA | 0.9218 | 0.2004 | 2648 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 9 | WORK.ANA_DATA | -0.4896 | 0.2005 | 2667 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 5 | WORK.ANA_DATA | -0.3442 | 0.2315 | 2648 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 6 | WORK.ANA_DATA | -1.8189 | 0.2009 | 2664 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 6 | WORK.ANA_DATA | -2.8792 | 0.1765 | 5649 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 6 | WORK.ANA_DATA | -2.3168 | 0.2315 | 2648 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 7 | WORK.ANA_DATA | -0.5753 | 0.2011 | 2671 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 7 | WORK.ANA_DATA | -1.4336 | 0.1776 | 5652 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 7 | WORK.ANA_DATA | -1.2693 | 0.2317 | 2655 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 8 | WORK.ANA_DATA | 1.7982 | 0.2013 | 2681 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 8 | WORK.ANA_DATA | 1.2465 | 0.1782 | 5654 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 8 | WORK.ANA_DATA | 0.3663 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 9 | WORK.ANA_DATA | 2.0294 | 0.2006 | 2655 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 9 | WORK.ANA_DATA | 1.8339 | 0.1763 | 5653 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 9 | WORK.ANA_DATA | 0.4225 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 6 | WORK.ANA_DATA | -1.4747 | 0.2002 | 2655 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 6 | WORK.ANA_DATA | -2.5349 | 0.2315 | 2648 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 6 | WORK.ANA_DATA | -1.9725 | 0.1755 | 5649 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 7 | WORK.ANA_DATA | -0.2311 | 0.2004 | 2662 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 7 | WORK.ANA_DATA | -1.0894 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 7 | WORK.ANA_DATA | -0.9251 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 8 | WORK.ANA_DATA | 2.1424 | 0.2007 | 2672 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 8 | WORK.ANA_DATA | 1.5907 | 0.2328 | 2691 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 8 | WORK.ANA_DATA | 0.7105 | 0.1766 | 5651 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 9 | WORK.ANA_DATA | 2.3736 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 9 | WORK.ANA_DATA | 2.1781 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 9 | WORK.ANA_DATA | 0.7667 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 6 | WORK.ANA_DATA | -1.0603 | 0.2009 | 2664 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 6 | WORK.ANA_DATA | -0.4979 | 0.2002 | 2655 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 7 | WORK.ANA_DATA | 1.2436 | 0.1253 | 5653 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 7 | WORK.ANA_DATA | 0.3853 | 0.2019 | 2702 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 7 | WORK.ANA_DATA | 0.5495 | 0.2005 | 2664 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 8 | WORK.ANA_DATA | 3.6171 | 0.1257 | 5654 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 8 | WORK.ANA_DATA | 3.0653 | 0.2024 | 2722 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 8 | WORK.ANA_DATA | 2.1851 | 0.2012 | 2692 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 9 | WORK.ANA_DATA | 3.8483 | 0.1247 | 5654 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 9 | WORK.ANA_DATA | 3.6528 | 0.2006 | 2655 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 9 | WORK.ANA_DATA | 2.2413 | 0.2007 | 2674 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 6 | WORK.ANA_DATA | 0.5624 | 0.2315 | 2648 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 7 | WORK.ANA_DATA | 2.3039 | 0.2011 | 2671 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 7 | WORK.ANA_DATA | 1.4456 | 0.1776 | 5652 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 7 | WORK.ANA_DATA | 1.6098 | 0.2317 | 2655 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 8 | WORK.ANA_DATA | 4.6774 | 0.2013 | 2681 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 8 | WORK.ANA_DATA | 4.1256 | 0.1782 | 5654 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 8 | WORK.ANA_DATA | 3.2454 | 0.2323 | 2676 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 4 | 2 | 9 | 18.22 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 9 | 15.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 5 | -4.54 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 5 | -6.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 6 | -21.89 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 6 | -18.89 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 6 | -16.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 7 | -11.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 7 | -11.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 7 | -10.89 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 8 | 7.06 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 8 | 1.65 | 0.0983 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 8 | -2.72 | 0.0067 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 9 | 8.98 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 9 | 4.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 9 | -2.44 | 0.0147 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 5 | -1.49 | 0.1371 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 6 | -9.05 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 6 | -16.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 6 | -10.01 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 7 | -2.86 | 0.0043 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 7 | -8.07 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 7 | -5.48 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 8 | 8.93 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 8 | 6.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 8 | 1.58 | 0.1150 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 9 | 10.11 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 9 | 10.40 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 9 | 1.82 | 0.0686 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 6 | -7.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 6 | -10.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 6 | -11.24 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 7 | -1.15 | 0.2491 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 7 | -4.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 7 | -5.26 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 8 | 10.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 8 | 6.83 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 8 | 4.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 9 | 11.87 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 9 | 9.42 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 9 | 4.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 6 | -5.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 6 | -2.49 | 0.0130 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 7 | 9.92 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 7 | 1.91 | 0.0565 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 7 | 2.74 | 0.0062 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 8 | 28.77 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 8 | 15.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 8 | 10.86 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 9 | 30.86 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 9 | 18.21 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 9 | 11.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 6 | 2.43 | 0.0152 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 7 | 11.46 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 7 | 8.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 7 | 6.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 8 | 23.23 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 8 | 23.15 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 8 | 13.97 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 4 | 2 | 9 | 3.7617 | 4.6693 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 9 | 2.4584 | 3.1497 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 5 | -1.3056 | -0.5185 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 5 | -1.6486 | -0.8640 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 6 | -2.9755 | -2.4864 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 6 | -4.1848 | -3.3976 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 6 | -3.6211 | -2.8365 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 7 | -1.7324 | -1.2422 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 7 | -2.7412 | -1.9501 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 7 | -2.5741 | -1.7886 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 8 | 0.6403 | 1.1321 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 8 | -0.06211 | 0.7309 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 8 | -0.9400 | -0.1516 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 9 | 0.8734 | 1.3613 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 9 | 0.5288 | 1.3149 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 9 | -0.8828 | -0.09636 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 5 | -0.7981 | 0.1096 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 6 | -2.2128 | -1.4250 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 6 | -3.2251 | -2.5332 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 6 | -2.7706 | -1.8629 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 7 | -0.9696 | -0.1810 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 7 | -1.7818 | -1.0854 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 7 | -1.7236 | -0.8151 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 8 | 1.4034 | 2.1930 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 8 | 0.8971 | 1.5958 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 8 | -0.08924 | 0.8217 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 9 | 1.6360 | 2.4228 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 9 | 1.4883 | 2.1795 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 9 | -0.03220 | 0.8771 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 6 | -1.8673 | -1.0820 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 6 | -2.9888 | -2.0811 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 6 | -2.3166 | -1.6285 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 7 | -0.6241 | 0.1619 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 7 | -1.5449 | -0.6338 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 7 | -1.2697 | -0.5806 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 8 | 1.7489 | 2.5359 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 8 | 1.1343 | 2.0471 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 8 | 0.3643 | 1.0567 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 9 | 1.9815 | 2.7658 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 9 | 1.7247 | 2.6315 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 9 | 0.4216 | 1.1118 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 6 | -1.4542 | -0.6664 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 6 | -0.8905 | -0.1053 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 7 | 0.9979 | 1.4893 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 7 | -0.01062 | 0.7811 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 7 | 0.1564 | 0.9426 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 8 | 3.3706 | 3.8635 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 8 | 2.6685 | 3.4622 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 8 | 1.7906 | 2.5797 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 9 | 3.6038 | 4.0928 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 9 | 3.2594 | 4.0461 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 9 | 1.8478 | 2.6349 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 6 | 0.1085 | 1.0163 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 7 | 1.9096 | 2.6982 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 7 | 1.0974 | 1.7937 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 7 | 1.1556 | 2.0641 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 8 | 4.2826 | 5.0722 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 8 | 3.7763 | 4.4750 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 8 | 2.7899 | 3.7009 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 2 | 6 | 1 | 9 | WORK.ANA_DATA | 4.9086 | 0.2006 | 2655 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 9 | WORK.ANA_DATA | 4.7131 | 0.1763 | 5653 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 9 | WORK.ANA_DATA | 3.3016 | 0.2319 | 2662 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 7 | WORK.ANA_DATA | 1.7415 | 0.2004 | 2662 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 7 | WORK.ANA_DATA | 0.8831 | 0.2323 | 2676 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 7 | WORK.ANA_DATA | 1.0474 | 0.1758 | 5650 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 8 | WORK.ANA_DATA | 4.1150 | 0.2007 | 2672 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 8 | WORK.ANA_DATA | 3.5632 | 0.2328 | 2691 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 8 | WORK.ANA_DATA | 2.6830 | 0.1766 | 5651 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 9 | WORK.ANA_DATA | 4.3462 | 0.2000 | 2646 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 9 | WORK.ANA_DATA | 4.1506 | 0.2312 | 2641 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 9 | WORK.ANA_DATA | 2.7392 | 0.1760 | 5650 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 7 | WORK.ANA_DATA | -0.8583 | 0.2021 | 2709 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 7 | WORK.ANA_DATA | -0.6940 | 0.2007 | 2671 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 8 | WORK.ANA_DATA | 2.3735 | 0.1260 | 5654 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 8 | WORK.ANA_DATA | 1.8218 | 0.2026 | 2729 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 8 | WORK.ANA_DATA | 0.9415 | 0.2014 | 2700 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 9 | WORK.ANA_DATA | 2.6047 | 0.1250 | 5655 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 9 | WORK.ANA_DATA | 2.4092 | 0.2008 | 2662 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 9 | WORK.ANA_DATA | 0.9978 | 0.2009 | 2681 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 7 | WORK.ANA_DATA | 0.1643 | 0.2325 | 2683 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 8 | WORK.ANA_DATA | 3.2318 | 0.2023 | 2719 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 8 | WORK.ANA_DATA | 2.6801 | 0.1792 | 5654 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 8 | WORK.ANA_DATA | 1.7999 | 0.2332 | 2704 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 9 | WORK.ANA_DATA | 3.4630 | 0.2016 | 2693 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 9 | WORK.ANA_DATA | 3.2675 | 0.1774 | 5656 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 9 | WORK.ANA_DATA | 1.8561 | 0.2327 | 2690 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 8 | WORK.ANA_DATA | 3.0675 | 0.2009 | 2681 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 8 | WORK.ANA_DATA | 2.5158 | 0.2330 | 2698 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 8 | WORK.ANA_DATA | 1.6356 | 0.1769 | 5652 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 9 | WORK.ANA_DATA | 3.2987 | 0.2002 | 2655 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 9 | WORK.ANA_DATA | 3.1032 | 0.2314 | 2648 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 9 | WORK.ANA_DATA | 1.6918 | 0.1763 | 5651 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 8 | WORK.ANA_DATA | -0.5517 | 0.2028 | 2738 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 8 | WORK.ANA_DATA | -1.4320 | 0.2016 | 2709 |
| TRTPN (ATPTN) | 1 | 8 | 1 | 9 | WORK.ANA_DATA | 0.2312 | 0.1254 | 5655 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 9 | WORK.ANA_DATA | 0.03568 | 0.2011 | 2672 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 9 | WORK.ANA_DATA | -1.3757 | 0.2012 | 2690 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 8 | WORK.ANA_DATA | -0.8802 | 0.2336 | 2719 |
| TRTPN (ATPTN) | 2 | 8 | 1 | 9 | WORK.ANA_DATA | 0.7829 | 0.2022 | 2712 |
| TRTPN (ATPTN) | 2 | 8 | 2 | 9 | WORK.ANA_DATA | 0.5874 | 0.1780 | 5658 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 9 | WORK.ANA_DATA | -0.8240 | 0.2332 | 2705 |
| TRTPN (ATPTN) | 3 | 8 | 1 | 9 | WORK.ANA_DATA | 1.6631 | 0.2010 | 2683 |
| TRTPN (ATPTN) | 3 | 8 | 2 | 9 | WORK.ANA_DATA | 1.4676 | 0.2320 | 2669 |
| TRTPN (ATPTN) | 3 | 8 | 3 | 9 | WORK.ANA_DATA | 0.05621 | 0.1771 | 5652 |
| TRTPN (ATPTN) | 1 | 9 | 2 | 9 | WORK.ANA_DATA | -0.1955 | 0.2004 | 2646 |
| TRTPN (ATPTN) | 1 | 9 | 3 | 9 | WORK.ANA_DATA | -1.6069 | 0.2005 | 2664 |
| TRTPN (ATPTN) | 2 | 9 | 3 | 9 | WORK.ANA_DATA | -1.4114 | 0.2316 | 2655 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 2 | 6 | 1 | 9 | 24.46 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 9 | 26.73 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 2 | 6 | 3 | 9 | 14.24 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 7 | 8.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 7 | 3.80 | 0.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 7 | 5.96 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 8 | 20.51 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 8 | 15.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 8 | 15.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 9 | 21.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 9 | 17.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 9 | 15.56 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 7 | -4.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 7 | -3.46 | 0.0006 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 8 | 18.84 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 8 | 8.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 8 | 4.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 9 | 20.84 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 9 | 12.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 9 | 4.97 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 7 | 0.71 | 0.4800 | 0.05 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 8 | 15.97 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 8 | 14.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 8 | 7.72 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 9 | 17.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 9 | 18.41 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 9 | 7.98 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 8 | 15.27 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 8 | 10.80 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 8 | 9.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 9 | 16.48 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 9 | 13.41 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 9 | 9.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 8 | -2.72 | 0.0066 | 0.05 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 8 | -7.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 8 | 1 | 9 | 1.84 | 0.0653 | 0.05 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 9 | 0.18 | 0.8592 | 0.05 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 9 | -6.84 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 8 | -3.77 | 0.0002 | 0.05 |
| TRTPN (ATPTN) | 2 | 8 | 1 | 9 | 3.87 | 0.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 8 | 2 | 9 | 3.30 | 0.0010 | 0.05 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 9 | -3.53 | 0.0004 | 0.05 |
| TRTPN (ATPTN) | 3 | 8 | 1 | 9 | 8.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 8 | 2 | 9 | 6.32 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 8 | 3 | 9 | 0.32 | 0.7510 | 0.05 |
| TRTPN (ATPTN) | 1 | 9 | 2 | 9 | -0.98 | 0.3293 | 0.05 |
| TRTPN (ATPTN) | 1 | 9 | 3 | 9 | -8.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 9 | 3 | 9 | -6.09 | <.0001 | 0.05 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|--------|--------|
| TRTPN (ATPTN) | 2 | 6 | 1 | 9 | 4.5151 | 5.3020 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 9 | 4.3674 | 5.0587 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 9 | 2.8470 | 3.7563 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 7 | 1.3485 | 2.1345 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|---------|
| TRTPN (ATPTN) | 3 | 6 | 2 | 7 | 0.4276 | 1.3387 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 7 | 0.7029 | 1.3920 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 8 | 3.7215 | 4.5085 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 8 | 3.1068 | 4.0197 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 8 | 2.3368 | 3.0292 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 9 | 3.9540 | 4.7383 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 9 | 3.6973 | 4.6040 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 9 | 2.3941 | 3.0843 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 7 | -1.2546 | -0.4621 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 7 | -1.0875 | -0.3006 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 8 | 2.1265 | 2.6205 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 8 | 1.4245 | 2.2190 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 8 | 0.5467 | 1.3364 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 9 | 2.3596 | 2.8498 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 9 | 2.0154 | 2.8029 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 9 | 0.6038 | 1.3917 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 7 | -0.2917 | 0.6202 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 8 | 2.8351 | 3.6286 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 8 | 2.3287 | 3.0315 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 8 | 1.3427 | 2.2571 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 9 | 3.0676 | 3.8584 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 9 | 2.9197 | 3.6154 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 9 | 1.3997 | 2.3125 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 8 | 2.6736 | 3.4615 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 8 | 2.0590 | 2.9726 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 8 | 1.2889 | 1.9823 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 9 | 2.9061 | 3.6914 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 9 | 2.6494 | 3.5570 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 9 | 1.3462 | 2.0374 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 8 | -0.9495 | -0.1540 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 8 | -1.8273 | -1.0366 |
| TRTPN (ATPTN) | 1 | 8 | 1 | 9 | -0.01462 | 0.4770 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 9 | -0.3586 | 0.4299 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 9 | -1.7702 | -0.9813 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 8 | -1.3383 | -0.4222 |
| TRTPN (ATPTN) | 2 | 8 | 1 | 9 | 0.3865 | 1.1793 |
| TRTPN (ATPTN) | 2 | 8 | 2 | 9 | 0.2384 | 0.9364 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 9 | -1.2812 | -0.3668 |
| TRTPN (ATPTN) | 3 | 8 | 1 | 9 | 1.2691 | 2.0572 |
| TRTPN (ATPTN) | 3 | 8 | 2 | 9 | 1.0126 | 1.9226 |
| TRTPN (ATPTN) | 3 | 8 | 3 | 9 | -0.2910 | 0.4035 |
| TRTPN (ATPTN) | 1 | 9 | 2 | 9 | -0.5884 | 0.1974 |
| TRTPN (ATPTN) | 1 | 9 | 3 | 9 | -2.0000 | -1.2139 |
| TRTPN (ATPTN) | 2 | 9 | 3 | 9 | -1.8656 | -0.9572 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------------|
| Data Set | WORK.ANA_DATA |
| Dependent Variable | AVAL |
| Covariance Structure | Compound Symmetry |
| Subject Effect | USUBJID |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Kenward-Roger |
| Degrees of Freedom Method | Kenward-Roger |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Number of Observations

Number of Observations Read 6480
 Number of Observations Used 6401
 Number of Observations Not Used 79

Iteration History

| Iteration | Evaluations | -2 Res Log Like | Criterion |
|-----------|-------------|-----------------|------------|
| 0 | 1 | 65035.29815169 | |
| 1 | 2 | 62992.58883544 | 0.00000000 |

Convergence criteria met.

Covariance Parameter Estimates

| Cov Parm | Subject | Estimate | Standard Error | Z Value | Pr > Z | Alpha | Lower | Upper |
|----------|---------|----------|----------------|---------|--------|-------|--------|--------|
| CS | USUBJID | 657.94 | 40.2013 | 16.37 | <.0001 | 0.05 | 579.15 | 736.73 |
| Residual | | 899.99 | 16.9343 | 53.15 | <.0001 | 0.05 | 867.70 | 934.12 |

Asymptotic Covariance Matrix of Estimates

| Row | Cov Parm | CovP1 | CovP2 |
|-----|----------|----------|----------|
| 1 | CS | 1616.14 | -32.4580 |
| 2 | Residual | -32.4580 | 286.77 |

Fit Statistics

-2 Res Log Likelihood 62992.6
 AIC (Smaller is Better) 62996.6
 AICC (Smaller is Better) 62996.6
 BIC (Smaller is Better) 63005.7

Null Model Likelihood Ratio Test

| DF | Chi-Square | Pr > ChiSq |
|----|------------|------------|
| 1 | 2042.71 | <.0001 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Estimate | Standard Error | DF | t Value | Pr > t |
|--------------|------------------------------------|-------------------------------------|------------------------|----------|----------------|------|---------|---------|
| Intercept | | | | 129.36 | 3.1296 | 2673 | 41.34 | <.0001 |
| TRTPN | | 1 | | -28.9569 | 3.6123 | 2664 | -8.02 | <.0001 |
| TRTPN | | 2 | | -25.4338 | 4.1740 | 2655 | -6.09 | <.0001 |
| TRTPN | | 3 | | 0 | | | | |
| TRTPN(ATPTN) | | 1 | 1 | 0.9972 | 2.4959 | 5650 | 0.40 | 0.6895 |
| TRTPN(ATPTN) | | 2 | 1 | 3.0880 | 3.3486 | 5649 | 0.92 | 0.3565 |
| TRTPN(ATPTN) | | 3 | 1 | 0.6433 | 3.3621 | 5650 | 0.19 | 0.8483 |
| TRTPN(ATPTN) | | 1 | 2 | 68.3246 | 2.4993 | 5650 | 27.34 | <.0001 |
| TRTPN(ATPTN) | | 2 | 2 | 80.2365 | 3.3670 | 5654 | 23.83 | <.0001 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Estimate | Standard Error | DF | t Value | Pr > t |
|-----------------|------------------------------------|-------------------------------------|------------------------|----------|----------------|------|---------|---------|
| TRTPN (ATPTN) | | 3 | 2 | 62.4258 | 3.3750 | 5652 | 18.50 | <.0001 |
| TRTPN (ATPTN) | | 1 | 3 | 20.3438 | 2.5061 | 5652 | 8.12 | <.0001 |
| TRTPN (ATPTN) | | 2 | 3 | 30.5109 | 3.3645 | 5654 | 9.07 | <.0001 |
| TRTPN (ATPTN) | | 3 | 3 | 16.7365 | 3.3632 | 5651 | 4.98 | <.0001 |
| TRTPN (ATPTN) | | 1 | 4 | 65.1838 | 2.5044 | 5651 | 26.03 | <.0001 |
| TRTPN (ATPTN) | | 2 | 4 | 85.5833 | 3.3675 | 5655 | 25.41 | <.0001 |
| TRTPN (ATPTN) | | 3 | 4 | 52.2188 | 3.3660 | 5651 | 15.51 | <.0001 |
| TRTPN (ATPTN) | | 1 | 5 | 22.7376 | 2.4997 | 5652 | 9.10 | <.0001 |
| TRTPN (ATPTN) | | 2 | 5 | 35.6495 | 3.3524 | 5652 | 10.63 | <.0001 |
| TRTPN (ATPTN) | | 3 | 5 | 16.4187 | 3.3632 | 5651 | 4.88 | <.0001 |
| TRTPN (ATPTN) | | 1 | 6 | 72.6059 | 2.5049 | 5653 | 28.99 | <.0001 |
| TRTPN (ATPTN) | | 2 | 6 | 88.1892 | 3.3528 | 5652 | 26.30 | <.0001 |
| TRTPN (ATPTN) | | 3 | 6 | 52.6208 | 3.3636 | 5651 | 15.64 | <.0001 |
| TRTPN (ATPTN) | | 1 | 7 | 50.3831 | 2.5089 | 5654 | 20.08 | <.0001 |
| TRTPN (ATPTN) | | 2 | 7 | 62.3271 | 3.3743 | 5655 | 18.47 | <.0001 |
| TRTPN (ATPTN) | | 3 | 7 | 33.9330 | 3.3706 | 5652 | 10.07 | <.0001 |
| TRTPN (ATPTN) | | 1 | 8 | 5.0699 | 2.5172 | 5654 | 2.01 | 0.0440 |
| TRTPN (ATPTN) | | 2 | 8 | 11.4891 | 3.3879 | 5657 | 3.39 | 0.0007 |
| TRTPN (ATPTN) | | 3 | 8 | 1.9167 | 3.3824 | 5653 | 0.57 | 0.5710 |
| TRTPN (ATPTN) | | 1 | 9 | 0 | | | | |
| TRTPN (ATPTN) | | 2 | 9 | 0 | | | | |
| TRTPN (ATPTN) | | 3 | 9 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 1 | -2.4780 | 3.1407 | 2641 | -0.79 | 0.4302 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 1 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 2 | -13.7059 | 3.1541 | 2671 | -4.35 | <.0001 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 2 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 3 | -10.4963 | 3.1518 | 2665 | -3.33 | 0.0009 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 3 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 4 | -8.8544 | 3.1571 | 2678 | -2.80 | 0.0051 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 4 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 5 | -11.6645 | 3.1514 | 2664 | -3.70 | 0.0002 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 5 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 6 | -13.6864 | 3.1557 | 2675 | -4.34 | <.0001 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 6 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 7 | -14.2607 | 3.1682 | 2705 | -4.50 | <.0001 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 7 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 8 | -6.4367 | 3.1817 | 2738 | -2.02 | 0.0432 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 8 | 0 | | | | |
| PREOAD2 (ATPTN) | Metformin | | 9 | -3.6559 | 3.1435 | 2648 | -1.16 | 0.2449 |
| PREOAD2 (ATPTN) | Metformin + OAD | | 9 | 0 | | | | |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|-----------------|--------|--------|---------|--------|
| TRTPN | 2 | 716 | 39.78 | <.0001 |
| TRTPN (ATPTN) | 16 | 5652 | 8.63 | <.0001 |
| PREOAD2 (ATPTN) | 9 | 5392 | 5.07 | <.0001 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|---------------|-------------------------------------|------------------------|---------------|----------|----------------|------|---------|---------|
| TRTPN (ATPTN) | 1 | 1 | WORK.ANA_DATA | 100.60 | 2.0774 | 2641 | 48.42 | <.0001 |
| TRTPN (ATPTN) | 2 | 1 | WORK.ANA_DATA | 106.21 | 2.9502 | 2641 | 36.00 | <.0001 |
| TRTPN (ATPTN) | 3 | 1 | WORK.ANA_DATA | 129.20 | 2.9420 | 2641 | 43.92 | <.0001 |
| TRTPN (ATPTN) | 1 | 2 | WORK.ANA_DATA | 164.28 | 2.0815 | 2655 | 78.92 | <.0001 |
| TRTPN (ATPTN) | 2 | 2 | WORK.ANA_DATA | 179.71 | 2.9730 | 2697 | 60.45 | <.0001 |
| TRTPN (ATPTN) | 3 | 2 | WORK.ANA_DATA | 187.33 | 2.9526 | 2669 | 63.45 | <.0001 |
| TRTPN (ATPTN) | 1 | 3 | WORK.ANA_DATA | 117.34 | 2.0873 | 2676 | 56.22 | <.0001 |
| TRTPN (ATPTN) | 2 | 3 | WORK.ANA_DATA | 131.03 | 2.9677 | 2683 | 44.15 | <.0001 |
| TRTPN (ATPTN) | 3 | 3 | WORK.ANA_DATA | 142.69 | 2.9420 | 2641 | 48.50 | <.0001 |
| TRTPN (ATPTN) | 1 | 4 | WORK.ANA_DATA | 162.71 | 2.0854 | 2669 | 78.03 | <.0001 |
| TRTPN (ATPTN) | 2 | 4 | WORK.ANA_DATA | 186.63 | 2.9732 | 2697 | 62.77 | <.0001 |
| TRTPN (ATPTN) | 3 | 4 | WORK.ANA_DATA | 178.70 | 2.9472 | 2655 | 60.63 | <.0001 |
| TRTPN (ATPTN) | 1 | 5 | WORK.ANA_DATA | 119.35 | 2.0834 | 2662 | 57.29 | <.0001 |
| TRTPN (ATPTN) | 2 | 5 | WORK.ANA_DATA | 135.79 | 2.9565 | 2654 | 45.93 | <.0001 |
| TRTPN (ATPTN) | 3 | 5 | WORK.ANA_DATA | 141.99 | 2.9420 | 2641 | 48.26 | <.0001 |
| TRTPN (ATPTN) | 1 | 6 | WORK.ANA_DATA | 168.56 | 2.0890 | 2683 | 80.69 | <.0001 |
| TRTPN (ATPTN) | 2 | 6 | WORK.ANA_DATA | 187.67 | 2.9565 | 2654 | 63.48 | <.0001 |
| TRTPN (ATPTN) | 3 | 6 | WORK.ANA_DATA | 177.54 | 2.9420 | 2641 | 60.35 | <.0001 |
| TRTPN (ATPTN) | 1 | 7 | WORK.ANA_DATA | 146.15 | 2.0948 | 2704 | 69.77 | <.0001 |
| TRTPN (ATPTN) | 2 | 7 | WORK.ANA_DATA | 161.62 | 2.9785 | 2712 | 54.26 | <.0001 |
| TRTPN (ATPTN) | 3 | 7 | WORK.ANA_DATA | 158.66 | 2.9472 | 2655 | 53.83 | <.0001 |
| TRTPN (ATPTN) | 1 | 8 | WORK.ANA_DATA | 103.38 | 2.1028 | 2733 | 49.17 | <.0001 |
| TRTPN (ATPTN) | 2 | 8 | WORK.ANA_DATA | 113.33 | 2.9898 | 2741 | 37.90 | <.0001 |
| TRTPN (ATPTN) | 3 | 8 | WORK.ANA_DATA | 129.19 | 2.9633 | 2697 | 43.60 | <.0001 |
| TRTPN (ATPTN) | 1 | 9 | WORK.ANA_DATA | 99.2172 | 2.0813 | 2655 | 47.67 | <.0001 |
| TRTPN (ATPTN) | 2 | 9 | WORK.ANA_DATA | 102.74 | 2.9502 | 2641 | 34.82 | <.0001 |
| TRTPN (ATPTN) | 3 | 9 | WORK.ANA_DATA | 128.17 | 2.9526 | 2669 | 43.41 | <.0001 |

Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Alpha | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------|---------|--------|
| TRTPN (ATPTN) | 1 | 1 | 0.05 | 96.5237 | 104.67 |
| TRTPN (ATPTN) | 2 | 1 | 0.05 | 100.43 | 112.00 |
| TRTPN (ATPTN) | 3 | 1 | 0.05 | 123.43 | 134.97 |
| TRTPN (ATPTN) | 1 | 2 | 0.05 | 160.19 | 168.36 |
| TRTPN (ATPTN) | 2 | 2 | 0.05 | 173.88 | 185.54 |
| TRTPN (ATPTN) | 3 | 2 | 0.05 | 181.54 | 193.12 |
| TRTPN (ATPTN) | 1 | 3 | 0.05 | 113.24 | 121.43 |
| TRTPN (ATPTN) | 2 | 3 | 0.05 | 125.21 | 136.85 |
| TRTPN (ATPTN) | 3 | 3 | 0.05 | 136.92 | 148.46 |
| TRTPN (ATPTN) | 1 | 4 | 0.05 | 158.62 | 166.80 |
| TRTPN (ATPTN) | 2 | 4 | 0.05 | 180.80 | 192.46 |
| TRTPN (ATPTN) | 3 | 4 | 0.05 | 172.92 | 184.48 |
| TRTPN (ATPTN) | 1 | 5 | 0.05 | 115.27 | 123.44 |
| TRTPN (ATPTN) | 2 | 5 | 0.05 | 129.99 | 141.58 |
| TRTPN (ATPTN) | 3 | 5 | 0.05 | 136.22 | 147.76 |
| TRTPN (ATPTN) | 1 | 6 | 0.05 | 164.47 | 172.66 |
| TRTPN (ATPTN) | 2 | 6 | 0.05 | 181.87 | 193.47 |
| TRTPN (ATPTN) | 3 | 6 | 0.05 | 171.77 | 183.30 |
| TRTPN (ATPTN) | 1 | 7 | 0.05 | 142.05 | 150.26 |
| TRTPN (ATPTN) | 2 | 7 | 0.05 | 155.78 | 167.46 |
| TRTPN (ATPTN) | 3 | 7 | 0.05 | 152.88 | 164.44 |
| TRTPN (ATPTN) | 1 | 8 | 0.05 | 99.2601 | 107.51 |
| TRTPN (ATPTN) | 2 | 8 | 0.05 | 107.46 | 119.19 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Alpha | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------|---------|--------|
| TRTPN (ATPTN) | 3 | 8 | 0.05 | 123.38 | 135.00 |
| TRTPN (ATPTN) | 1 | 9 | 0.05 | 95.1361 | 103.30 |
| TRTPN (ATPTN) | 2 | 9 | 0.05 | 96.9553 | 108.53 |
| TRTPN (ATPTN) | 3 | 9 | 0.05 | 122.38 | 133.96 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 1 | 1 | 2 | 1 | WORK.ANA_DATA | -5.6140 | 3.6083 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 1 | WORK.ANA_DATA | -28.6031 | 3.6015 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 2 | WORK.ANA_DATA | -63.6784 | 2.2368 | 5652 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 2 | WORK.ANA_DATA | -79.1134 | 3.6269 | 2679 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 2 | WORK.ANA_DATA | -86.7365 | 3.6102 | 2660 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 3 | WORK.ANA_DATA | -16.7407 | 2.2422 | 5653 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 3 | WORK.ANA_DATA | -30.4309 | 3.6225 | 2669 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 3 | WORK.ANA_DATA | -42.0903 | 3.6015 | 2641 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 1 | 1 | 2 | 1 | -1.56 | 0.1199 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 1 | -7.94 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 2 | -28.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 2 | -21.81 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 2 | -24.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 3 | -7.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 3 | -8.40 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 3 | -11.69 | <.0001 | 0.05 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 1 | 1 | 2 | 1 | -12.6893 | 1.4614 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 1 | -35.6651 | -21.5411 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 2 | -68.0634 | -59.2934 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 2 | -86.2253 | -72.0016 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 2 | -93.8155 | -79.6575 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 3 | -21.1361 | -12.3452 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 3 | -37.5342 | -23.3276 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 3 | -49.1524 | -35.0283 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGC0L

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 1 | 1 | 1 | 4 | WORK.ANA_DATA | -62.1143 | 2.2404 | 5653 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 4 | WORK.ANA_DATA | -86.0370 | 3.6271 | 2679 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 4 | WORK.ANA_DATA | -78.1063 | 3.6058 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 5 | WORK.ANA_DATA | -18.7548 | 2.2386 | 5652 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 5 | WORK.ANA_DATA | -35.1898 | 3.6134 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 5 | WORK.ANA_DATA | -41.3928 | 3.6015 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 6 | WORK.ANA_DATA | -67.9660 | 2.2438 | 5653 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 6 | WORK.ANA_DATA | -87.0725 | 3.6134 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 6 | WORK.ANA_DATA | -76.9379 | 3.6015 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 7 | WORK.ANA_DATA | -45.5566 | 2.2492 | 5654 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 7 | WORK.ANA_DATA | -61.0237 | 3.6314 | 2688 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 7 | WORK.ANA_DATA | -58.0633 | 3.6058 | 2650 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 8 | WORK.ANA_DATA | -2.7861 | 2.2566 | 5656 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 8 | WORK.ANA_DATA | -12.7285 | 3.6407 | 2708 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 8 | WORK.ANA_DATA | -28.5899 | 3.6189 | 2679 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 9 | WORK.ANA_DATA | 1.3800 | 2.2365 | 5650 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 9 | WORK.ANA_DATA | -2.1432 | 3.6083 | 2641 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 9 | WORK.ANA_DATA | -27.5769 | 3.6102 | 2660 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 1 | WORK.ANA_DATA | -22.9891 | 4.1665 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 2 | WORK.ANA_DATA | -58.0644 | 3.6107 | 2645 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 2 | WORK.ANA_DATA | -73.4995 | 3.1924 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 2 | WORK.ANA_DATA | -81.1225 | 4.1739 | 2655 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 3 | WORK.ANA_DATA | -11.1267 | 3.6140 | 2652 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 3 | WORK.ANA_DATA | -24.8169 | 3.1874 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 3 | WORK.ANA_DATA | -36.4764 | 4.1664 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 4 | WORK.ANA_DATA | -56.5004 | 3.6129 | 2650 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 4 | WORK.ANA_DATA | -80.4230 | 3.1925 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 4 | WORK.ANA_DATA | -72.4923 | 4.1702 | 2648 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 5 | WORK.ANA_DATA | -13.1408 | 3.6118 | 2648 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 5 | WORK.ANA_DATA | -29.5759 | 3.1770 | 5653 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 5 | WORK.ANA_DATA | -35.7788 | 4.1664 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 6 | WORK.ANA_DATA | -62.3520 | 3.6150 | 2655 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 6 | WORK.ANA_DATA | -81.4585 | 3.1770 | 5653 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 6 | WORK.ANA_DATA | -71.3239 | 4.1664 | 2641 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 7 | WORK.ANA_DATA | -39.9426 | 3.6183 | 2662 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 7 | WORK.ANA_DATA | -55.4097 | 3.1974 | 5656 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 7 | WORK.ANA_DATA | -52.4494 | 4.1702 | 2648 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 8 | WORK.ANA_DATA | 2.8278 | 3.6229 | 2672 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 8 | WORK.ANA_DATA | -7.1146 | 3.2079 | 5658 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 8 | WORK.ANA_DATA | -22.9760 | 4.1815 | 2669 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 9 | WORK.ANA_DATA | 6.9940 | 3.6105 | 2646 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 9 | WORK.ANA_DATA | 3.4708 | 3.1711 | 5649 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 9 | WORK.ANA_DATA | -21.9630 | 4.1739 | 2655 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 2 | WORK.ANA_DATA | -35.0753 | 3.6039 | 2646 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 2 | WORK.ANA_DATA | -50.5103 | 4.1826 | 2669 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 2 | WORK.ANA_DATA | -58.1334 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 3 | WORK.ANA_DATA | 11.8625 | 3.6072 | 2653 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 3 | WORK.ANA_DATA | -1.8278 | 4.1788 | 2662 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 3 | WORK.ANA_DATA | -13.4872 | 3.1623 | 5649 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 4 | WORK.ANA_DATA | -33.5112 | 3.6061 | 2650 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 4 | WORK.ANA_DATA | -57.4339 | 4.1827 | 2669 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 4 | WORK.ANA_DATA | -49.5032 | 3.1671 | 5650 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 5 | WORK.ANA_DATA | 9.8483 | 3.6050 | 2648 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 5 | WORK.ANA_DATA | -6.5867 | 4.1709 | 2648 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 5 | WORK.ANA_DATA | -12.7897 | 3.1623 | 5649 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 6 | WORK.ANA_DATA | -39.3629 | 3.6082 | 2655 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 6 | WORK.ANA_DATA | -58.4694 | 4.1709 | 2648 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 6 | WORK.ANA_DATA | -48.3347 | 3.1623 | 5649 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 7 | WORK.ANA_DATA | -16.9535 | 3.6116 | 2662 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 1 | 1 | 1 | 4 | -27.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 4 | -23.72 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 4 | -21.66 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 5 | -8.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 5 | -9.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 5 | -11.49 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 6 | -30.29 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 6 | -24.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 6 | -21.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 7 | -20.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 7 | -16.80 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 7 | -16.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 8 | -1.23 | 0.2170 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 8 | -3.50 | 0.0005 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 8 | -7.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 9 | 0.62 | 0.5372 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 9 | -0.59 | 0.5526 | 0.05 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 9 | -7.64 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 1 | -5.52 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 2 | -16.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 2 | -23.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 2 | -19.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 3 | -3.08 | 0.0021 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 3 | -7.79 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 3 | -8.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 4 | -15.64 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 4 | -25.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 4 | -17.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 5 | -3.64 | 0.0003 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 5 | -9.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 5 | -8.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 6 | -17.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 6 | -25.64 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 6 | -17.12 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 7 | -11.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 7 | -17.33 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 7 | -12.58 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 8 | 0.78 | 0.4351 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 8 | -2.22 | 0.0266 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 8 | -5.49 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 9 | 1.94 | 0.0528 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 9 | 1.09 | 0.2738 | 0.05 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 9 | -5.26 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 2 | -9.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 2 | -12.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 2 | -18.33 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 3 | 3.29 | 0.0010 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 3 | -0.44 | 0.6619 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 3 | -4.27 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 4 | -9.29 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 4 | -13.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 4 | -15.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 5 | 2.73 | 0.0063 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 5 | -1.58 | 0.1144 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 5 | -4.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 6 | -10.91 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 6 | -14.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 6 | -15.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 7 | -4.69 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 1 | 1 | 1 | 4 | -66.5063 | -57.7224 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 4 | -93.1492 | -78.9249 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 4 | -85.1767 | -71.0359 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 5 | -23.1432 | -14.3663 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 5 | -42.2752 | -28.1044 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 5 | -48.4548 | -34.3307 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 6 | -72.3647 | -63.5673 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 6 | -94.1579 | -79.9871 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 6 | -83.9999 | -69.8758 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 7 | -49.9658 | -41.1473 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 7 | -68.1443 | -53.9031 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 7 | -65.1338 | -50.9929 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 8 | -7.2099 | 1.6376 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 8 | -19.8673 | -5.5898 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 8 | -35.6861 | -21.4938 |
| TRTPN (ATPTN) | 1 | 1 | 1 | 9 | -3.0045 | 5.7645 |
| TRTPN (ATPTN) | 1 | 1 | 2 | 9 | -9.2185 | 4.9322 |
| TRTPN (ATPTN) | 1 | 1 | 3 | 9 | -34.6559 | -20.4980 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 1 | -31.1590 | -14.8193 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 2 | -65.1444 | -50.9844 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 2 | -79.7577 | -67.2412 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 2 | -89.3070 | -72.9380 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 3 | -18.2132 | -4.0402 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 3 | -31.0654 | -18.5684 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 3 | -44.6462 | -28.3065 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 4 | -63.5847 | -49.4161 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 4 | -86.6816 | -74.1645 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 4 | -80.6694 | -64.3152 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 5 | -20.2230 | -6.0587 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 5 | -35.8040 | -23.3477 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 5 | -43.9487 | -27.6090 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 6 | -69.4405 | -55.2636 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 6 | -87.6867 | -75.2304 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 6 | -79.4937 | -63.1541 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 7 | -47.0376 | -32.8476 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 7 | -61.6779 | -49.1415 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 7 | -60.6265 | -44.2723 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 8 | -4.2762 | 9.9319 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 8 | -13.4034 | -0.8258 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 8 | -31.1753 | -14.7766 |
| TRTPN (ATPTN) | 2 | 1 | 1 | 9 | -0.08570 | 14.0736 |
| TRTPN (ATPTN) | 2 | 1 | 2 | 9 | -2.7459 | 9.6875 |
| TRTPN (ATPTN) | 2 | 1 | 3 | 9 | -30.1475 | -13.7785 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 2 | -42.1420 | -28.0085 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 2 | -58.7118 | -42.3088 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 2 | -64.3520 | -51.9148 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 3 | 4.7892 | 18.9357 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 3 | -10.0218 | 6.3663 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 3 | -19.6865 | -7.2880 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 4 | -40.5823 | -26.4402 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 4 | -65.6356 | -49.2322 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 4 | -55.7120 | -43.2944 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 5 | 2.7795 | 16.9172 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 5 | -14.7653 | 1.5918 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 5 | -18.9889 | -6.5904 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 6 | -46.4381 | -32.2877 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 6 | -66.6479 | -50.2908 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 6 | -54.5340 | -42.1355 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 7 | -24.0353 | -9.8717 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 1 | 2 | 7 | WORK.ANA_DATA | -32.4206 | 4.1865 | 2676 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 7 | WORK.ANA_DATA | -29.4602 | 3.1672 | 5650 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 8 | WORK.ANA_DATA | 25.8170 | 3.6162 | 2672 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 8 | WORK.ANA_DATA | 15.8746 | 4.1945 | 2691 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 8 | WORK.ANA_DATA | 0.01317 | 3.1821 | 5651 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 9 | WORK.ANA_DATA | 29.9831 | 3.6037 | 2646 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 9 | WORK.ANA_DATA | 26.4599 | 4.1664 | 2641 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 9 | WORK.ANA_DATA | 1.0262 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 2 | WORK.ANA_DATA | -15.4350 | 3.6293 | 2683 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 2 | WORK.ANA_DATA | -23.0581 | 3.6125 | 2664 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 3 | WORK.ANA_DATA | 46.9377 | 2.2445 | 5650 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 3 | WORK.ANA_DATA | 33.2475 | 3.6249 | 2673 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 3 | WORK.ANA_DATA | 21.5880 | 3.6039 | 2646 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 4 | WORK.ANA_DATA | 1.5640 | 2.2427 | 5650 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 4 | WORK.ANA_DATA | -22.3586 | 3.6294 | 2683 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 4 | WORK.ANA_DATA | -14.4279 | 3.6082 | 2655 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 5 | WORK.ANA_DATA | 44.9236 | 2.2415 | 5651 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 5 | WORK.ANA_DATA | 28.4885 | 3.6158 | 2654 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 5 | WORK.ANA_DATA | 22.2856 | 3.6039 | 2646 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 6 | WORK.ANA_DATA | -4.2876 | 2.2467 | 5652 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 6 | WORK.ANA_DATA | -23.3941 | 3.6158 | 2654 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 6 | WORK.ANA_DATA | -13.2595 | 3.6039 | 2646 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 7 | WORK.ANA_DATA | 18.1218 | 2.2521 | 5653 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 7 | WORK.ANA_DATA | 2.6547 | 3.6338 | 2693 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 7 | WORK.ANA_DATA | 5.6150 | 3.6082 | 2655 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 8 | WORK.ANA_DATA | 60.8922 | 2.2589 | 5653 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 8 | WORK.ANA_DATA | 50.9498 | 3.6430 | 2712 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 8 | WORK.ANA_DATA | 35.0884 | 3.6213 | 2683 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 9 | WORK.ANA_DATA | 65.0584 | 2.2398 | 5651 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 9 | WORK.ANA_DATA | 61.5352 | 3.6107 | 2645 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 9 | WORK.ANA_DATA | 36.1014 | 3.6125 | 2664 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 2 | WORK.ANA_DATA | -7.6231 | 4.1902 | 2683 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 3 | WORK.ANA_DATA | 62.3728 | 3.6326 | 2690 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 3 | WORK.ANA_DATA | 48.6825 | 3.2044 | 5652 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 3 | WORK.ANA_DATA | 37.0231 | 4.1826 | 2669 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 4 | WORK.ANA_DATA | 16.9991 | 3.6315 | 2688 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 4 | WORK.ANA_DATA | -6.9236 | 3.2096 | 5652 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 4 | WORK.ANA_DATA | 1.0071 | 4.1863 | 2676 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 5 | WORK.ANA_DATA | 60.3586 | 3.6304 | 2685 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 5 | WORK.ANA_DATA | 43.9236 | 3.1955 | 5651 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 5 | WORK.ANA_DATA | 37.7206 | 4.1826 | 2669 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 6 | WORK.ANA_DATA | 11.1474 | 3.6336 | 2692 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 6 | WORK.ANA_DATA | -7.9591 | 3.1955 | 5651 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 6 | WORK.ANA_DATA | 2.1756 | 4.1826 | 2669 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 7 | WORK.ANA_DATA | 33.5568 | 3.6369 | 2699 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 7 | WORK.ANA_DATA | 18.0897 | 3.2148 | 5653 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 7 | WORK.ANA_DATA | 21.0501 | 4.1863 | 2676 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 8 | WORK.ANA_DATA | 76.3273 | 3.6415 | 2709 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 8 | WORK.ANA_DATA | 66.3849 | 3.2250 | 5654 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 8 | WORK.ANA_DATA | 50.5235 | 4.1976 | 2697 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 9 | WORK.ANA_DATA | 80.4934 | 3.6291 | 2683 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 9 | WORK.ANA_DATA | 76.9702 | 3.1924 | 5656 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 9 | WORK.ANA_DATA | 51.5365 | 4.1901 | 2683 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 3 | WORK.ANA_DATA | 69.9958 | 3.6158 | 2671 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 3 | WORK.ANA_DATA | 56.3056 | 4.1863 | 2676 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 3 | WORK.ANA_DATA | 44.6462 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 4 | WORK.ANA_DATA | 24.6221 | 3.6147 | 2669 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 4 | WORK.ANA_DATA | 0.6995 | 4.1902 | 2683 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 4 | WORK.ANA_DATA | 8.6302 | 3.1770 | 5651 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 1 | 2 | 7 | -7.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 7 | -9.30 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 8 | 7.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 8 | 3.78 | 0.0002 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 8 | 0.00 | 0.9967 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 9 | 8.32 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 9 | 6.35 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 9 | 0.32 | 0.7463 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 2 | -4.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 2 | -6.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 3 | 20.91 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 3 | 9.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 3 | 5.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 4 | 0.70 | 0.4856 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 4 | -6.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 4 | -4.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 5 | 20.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 5 | 7.88 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 5 | 6.18 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 6 | -1.91 | 0.0564 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 6 | -6.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 6 | -3.68 | 0.0002 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 7 | 8.05 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 7 | 0.73 | 0.4651 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 7 | 1.56 | 0.1198 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 8 | 26.96 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 8 | 13.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 8 | 9.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 9 | 29.05 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 9 | 17.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 9 | 9.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 2 | -1.82 | 0.0690 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 3 | 17.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 3 | 15.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 3 | 8.85 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 4 | 4.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 4 | -2.16 | 0.0310 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 4 | 0.24 | 0.8099 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 5 | 16.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 5 | 13.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 5 | 9.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 6 | 3.07 | 0.0022 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 6 | -2.49 | 0.0128 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 6 | 0.52 | 0.6030 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 7 | 9.23 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 7 | 5.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 7 | 5.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 8 | 20.96 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 8 | 20.58 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 8 | 12.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 9 | 22.18 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 9 | 24.11 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 9 | 12.30 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 3 | 19.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 3 | 13.45 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 3 | 14.07 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 4 | 6.81 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 4 | 0.17 | 0.8674 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 4 | 2.72 | 0.0066 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 1 | 2 | 7 | -40.6297 | -24.2115 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 7 | -35.6691 | -23.2514 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 8 | 18.7262 | 32.9078 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 8 | 7.6498 | 24.0994 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 8 | -6.2249 | 6.2513 |
| TRTPN (ATPTN) | 3 | 1 | 1 | 9 | 22.9167 | 37.0495 |
| TRTPN (ATPTN) | 3 | 1 | 2 | 9 | 18.2901 | 34.6298 |
| TRTPN (ATPTN) | 3 | 1 | 3 | 9 | -5.1924 | 7.2447 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 2 | -22.5516 | -8.3185 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 2 | -30.1418 | -15.9745 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 3 | 42.5376 | 51.3378 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 3 | 26.1395 | 40.3554 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 3 | 14.5213 | 28.6548 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 4 | -2.8325 | 5.9606 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 4 | -29.4754 | -15.2419 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 4 | -21.5030 | -7.3528 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 5 | 40.5294 | 49.3178 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 5 | 21.3985 | 35.5786 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 5 | 15.2188 | 29.3523 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 6 | -8.6921 | 0.1168 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 6 | -30.4842 | -16.3041 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 6 | -20.3262 | -6.1928 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 7 | 13.7068 | 22.5368 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 7 | -4.4706 | 9.7799 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 7 | -1.4601 | 12.6902 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 8 | 56.4639 | 65.3206 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 8 | 43.8065 | 58.0932 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 8 | 27.9876 | 42.1892 |
| TRTPN (ATPTN) | 1 | 2 | 1 | 9 | 60.6675 | 69.4493 |
| TRTPN (ATPTN) | 1 | 2 | 2 | 9 | 54.4552 | 68.6152 |
| TRTPN (ATPTN) | 1 | 2 | 3 | 9 | 29.0178 | 43.1851 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 2 | -15.8394 | 0.5932 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 3 | 55.2498 | 69.4957 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 3 | 42.4006 | 54.9645 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 3 | 28.8216 | 45.2246 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 4 | 9.8783 | 24.1198 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 4 | -13.2156 | -0.6316 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 4 | -7.2016 | 9.2158 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 5 | 53.2400 | 67.4773 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 5 | 37.6592 | 50.1880 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 5 | 29.5191 | 45.9221 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 6 | 4.0225 | 18.2723 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 6 | -14.2235 | -1.6947 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 6 | -6.0259 | 10.3771 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 7 | 26.4254 | 40.6883 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 7 | 11.7875 | 24.3920 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 7 | 12.8413 | 29.2588 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 8 | 69.1869 | 83.4677 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 8 | 60.0627 | 72.7070 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 8 | 42.2926 | 58.7544 |
| TRTPN (ATPTN) | 2 | 2 | 1 | 9 | 73.3773 | 87.6096 |
| TRTPN (ATPTN) | 2 | 2 | 2 | 9 | 70.7120 | 83.2285 |
| TRTPN (ATPTN) | 2 | 2 | 3 | 9 | 43.3204 | 59.7525 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 3 | 62.9057 | 77.0860 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 3 | 48.0969 | 64.5143 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 3 | 38.4276 | 50.8647 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 4 | 17.5342 | 31.7101 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 4 | -7.5169 | 8.9158 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 4 | 2.4021 | 14.8583 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 2 | 1 | 5 | WORK.ANA_DATA | 67.9817 | 3.6136 | 2667 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 5 | WORK.ANA_DATA | 51.5467 | 4.1784 | 2662 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 5 | WORK.ANA_DATA | 45.3437 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 6 | WORK.ANA_DATA | 18.7705 | 3.6169 | 2674 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 6 | WORK.ANA_DATA | -0.3360 | 4.1784 | 2662 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 6 | WORK.ANA_DATA | 9.7986 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 7 | WORK.ANA_DATA | 41.1799 | 3.6202 | 2681 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 7 | WORK.ANA_DATA | 25.7128 | 4.1939 | 2690 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 7 | WORK.ANA_DATA | 28.6731 | 3.1770 | 5651 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 8 | WORK.ANA_DATA | 83.9504 | 3.6248 | 2690 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 8 | WORK.ANA_DATA | 74.0080 | 4.2020 | 2705 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 8 | WORK.ANA_DATA | 58.1466 | 3.1919 | 5652 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 9 | WORK.ANA_DATA | 88.1165 | 3.6124 | 2664 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 9 | WORK.ANA_DATA | 84.5933 | 4.1739 | 2655 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 9 | WORK.ANA_DATA | 59.1595 | 3.1820 | 5651 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 3 | WORK.ANA_DATA | -13.6902 | 3.6283 | 2680 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 3 | WORK.ANA_DATA | -25.3497 | 3.6072 | 2653 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 4 | WORK.ANA_DATA | -45.3737 | 2.2477 | 5650 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 4 | WORK.ANA_DATA | -69.2964 | 3.6327 | 2690 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 4 | WORK.ANA_DATA | -61.3656 | 3.6115 | 2662 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 5 | WORK.ANA_DATA | -2.0141 | 2.2463 | 5651 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 5 | WORK.ANA_DATA | -18.4492 | 3.6191 | 2661 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 5 | WORK.ANA_DATA | -24.6521 | 3.6072 | 2653 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 6 | WORK.ANA_DATA | -51.2254 | 2.2521 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 6 | WORK.ANA_DATA | -70.3318 | 3.6191 | 2661 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 6 | WORK.ANA_DATA | -60.1972 | 3.6072 | 2653 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 7 | WORK.ANA_DATA | -28.8159 | 2.2569 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 7 | WORK.ANA_DATA | -44.2830 | 3.6371 | 2700 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 7 | WORK.ANA_DATA | -41.3227 | 3.6115 | 2662 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 8 | WORK.ANA_DATA | 13.9545 | 2.2637 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 8 | WORK.ANA_DATA | 4.0121 | 3.6463 | 2719 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 8 | WORK.ANA_DATA | -11.8493 | 3.6246 | 2690 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 9 | WORK.ANA_DATA | 18.1207 | 2.2451 | 5653 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 9 | WORK.ANA_DATA | 14.5975 | 3.6140 | 2652 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 9 | WORK.ANA_DATA | -10.8363 | 3.6158 | 2671 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 3 | WORK.ANA_DATA | -11.6594 | 4.1788 | 2662 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 4 | WORK.ANA_DATA | -31.6834 | 3.6271 | 2678 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 4 | WORK.ANA_DATA | -55.6061 | 3.2032 | 5650 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 4 | WORK.ANA_DATA | -47.6754 | 4.1825 | 2669 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 5 | WORK.ANA_DATA | 11.6761 | 3.6260 | 2676 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 5 | WORK.ANA_DATA | -4.7589 | 3.1905 | 5651 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 5 | WORK.ANA_DATA | -10.9619 | 4.1788 | 2662 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 6 | WORK.ANA_DATA | -37.5351 | 3.6292 | 2683 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 6 | WORK.ANA_DATA | -56.6416 | 3.1905 | 5651 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 6 | WORK.ANA_DATA | -46.5070 | 4.1788 | 2662 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 7 | WORK.ANA_DATA | -15.1257 | 3.6326 | 2690 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 7 | WORK.ANA_DATA | -30.5928 | 3.2095 | 5652 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 7 | WORK.ANA_DATA | -27.6324 | 4.1825 | 2669 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 8 | WORK.ANA_DATA | 27.6448 | 3.6371 | 2699 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 8 | WORK.ANA_DATA | 17.7024 | 3.2186 | 5651 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 8 | WORK.ANA_DATA | 1.8410 | 4.1938 | 2690 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 9 | WORK.ANA_DATA | 31.8109 | 3.6248 | 2673 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 9 | WORK.ANA_DATA | 28.2877 | 3.1874 | 5656 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 9 | WORK.ANA_DATA | 2.8540 | 4.1863 | 2676 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 4 | WORK.ANA_DATA | -20.0240 | 3.6061 | 2650 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 4 | WORK.ANA_DATA | -43.9467 | 4.1827 | 2669 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 4 | WORK.ANA_DATA | -36.0160 | 3.1671 | 5650 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 5 | WORK.ANA_DATA | 23.3356 | 3.6050 | 2648 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 5 | WORK.ANA_DATA | 6.9005 | 4.1709 | 2648 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 2 | 1 | 5 | 18.81 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 5 | 12.34 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 5 | 14.29 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 6 | 5.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 6 | -0.08 | 0.9359 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 6 | 3.09 | 0.0020 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 7 | 11.38 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 7 | 6.13 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 7 | 9.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 8 | 23.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 8 | 17.61 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 8 | 18.22 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 9 | 24.39 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 9 | 20.27 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 9 | 18.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 3 | -3.77 | 0.0002 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 3 | -7.03 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 4 | -20.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 4 | -19.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 4 | -16.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 5 | -0.90 | 0.3700 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 5 | -5.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 5 | -6.83 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 6 | -22.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 6 | -19.43 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 6 | -16.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 7 | -12.77 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 7 | -12.18 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 7 | -11.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 8 | 6.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 8 | 1.10 | 0.2713 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 8 | -3.27 | 0.0011 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 9 | 8.07 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 9 | 4.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 9 | -3.00 | 0.0028 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 3 | -2.79 | 0.0053 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 4 | -8.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 4 | -17.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 4 | -11.40 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 5 | 3.22 | 0.0013 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 5 | -1.49 | 0.1359 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 5 | -2.62 | 0.0088 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 6 | -10.34 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 6 | -17.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 6 | -11.13 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 7 | -4.16 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 7 | -9.53 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 7 | -6.61 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 8 | 7.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 8 | 5.50 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 8 | 0.44 | 0.6607 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 9 | 8.78 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 9 | 8.87 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 9 | 0.68 | 0.4955 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 4 | -5.55 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 4 | -10.51 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 4 | -11.37 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 5 | 6.47 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 5 | 1.65 | 0.0982 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 2 | 1 | 5 | 60.8959 | 75.0675 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 5 | 43.3535 | 59.7399 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 5 | 39.1251 | 51.5623 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 6 | 11.6784 | 25.8626 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 6 | -8.5292 | 7.8572 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 6 | 3.5801 | 16.0172 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 7 | 34.0812 | 48.2786 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 7 | 17.4891 | 33.9365 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 7 | 22.4450 | 34.9013 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 8 | 76.8427 | 91.0580 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 8 | 65.7686 | 82.2473 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 8 | 51.8892 | 64.4039 |
| TRTPN (ATPTN) | 3 | 2 | 1 | 9 | 81.0332 | 95.1998 |
| TRTPN (ATPTN) | 3 | 2 | 2 | 9 | 76.4088 | 92.7778 |
| TRTPN (ATPTN) | 3 | 2 | 3 | 9 | 52.9217 | 65.3974 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 3 | -20.8047 | -6.5758 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 3 | -32.4229 | -18.2765 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 4 | -49.7800 | -40.9674 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 4 | -76.4196 | -62.1731 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 4 | -68.4472 | -54.2840 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 5 | -6.4178 | 2.3896 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 5 | -25.5457 | -11.3526 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 5 | -31.7254 | -17.5789 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 6 | -55.6402 | -46.8105 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 6 | -77.4284 | -63.2353 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 6 | -67.2704 | -53.1240 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 7 | -33.2404 | -24.3914 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 7 | -51.4147 | -37.1513 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 7 | -48.4043 | -34.2411 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 8 | 9.5168 | 18.3923 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 8 | -3.1377 | 11.1619 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 8 | -18.9565 | -4.7420 |
| TRTPN (ATPTN) | 1 | 3 | 1 | 9 | 13.7193 | 22.5220 |
| TRTPN (ATPTN) | 1 | 3 | 2 | 9 | 7.5110 | 21.6840 |
| TRTPN (ATPTN) | 1 | 3 | 3 | 9 | -17.9264 | -3.7462 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 3 | -19.8535 | -3.4653 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 4 | -38.7957 | -24.5712 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 4 | -61.8856 | -49.3266 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 4 | -55.8767 | -39.4741 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 5 | 4.5661 | 18.7862 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 5 | -11.0136 | 1.4957 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 5 | -19.1560 | -2.7678 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 6 | -44.6515 | -30.4187 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 6 | -62.8963 | -50.3869 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 6 | -54.7010 | -38.3129 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 7 | -22.2486 | -8.0028 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 7 | -36.8847 | -24.3009 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 7 | -35.8338 | -19.4311 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 8 | 20.5129 | 34.7766 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 8 | 11.3927 | 24.0120 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 8 | -6.3825 | 10.0644 |
| TRTPN (ATPTN) | 2 | 3 | 1 | 9 | 24.7033 | 38.9185 |
| TRTPN (ATPTN) | 2 | 3 | 2 | 9 | 22.0392 | 34.5362 |
| TRTPN (ATPTN) | 2 | 3 | 3 | 9 | -5.3547 | 11.0626 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 4 | -27.0951 | -12.9530 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 4 | -52.1484 | -35.7450 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 4 | -42.2248 | -29.8071 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 5 | 16.2667 | 30.4044 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 5 | -1.2781 | 15.0791 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 3 | 3 | 5 | WORK.ANA_DATA | 0.6975 | 3.1623 | 5649 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 6 | WORK.ANA_DATA | -25.8757 | 3.6082 | 2655 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 6 | WORK.ANA_DATA | -44.9822 | 4.1709 | 2648 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 6 | WORK.ANA_DATA | -34.8475 | 3.1623 | 5649 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 7 | WORK.ANA_DATA | -3.4662 | 3.6116 | 2662 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 7 | WORK.ANA_DATA | -18.9334 | 4.1865 | 2676 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 7 | WORK.ANA_DATA | -15.9730 | 3.1672 | 5650 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 8 | WORK.ANA_DATA | 39.3042 | 3.6162 | 2672 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 8 | WORK.ANA_DATA | 29.3618 | 4.1945 | 2691 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 8 | WORK.ANA_DATA | 13.5004 | 3.1821 | 5651 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 9 | WORK.ANA_DATA | 43.4703 | 3.6037 | 2646 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 9 | WORK.ANA_DATA | 39.9472 | 4.1664 | 2641 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 9 | WORK.ANA_DATA | 14.5134 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 4 | WORK.ANA_DATA | -23.9227 | 3.6317 | 2688 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 4 | WORK.ANA_DATA | -15.9919 | 3.6104 | 2659 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 5 | WORK.ANA_DATA | 43.3596 | 2.2451 | 5652 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 5 | WORK.ANA_DATA | 26.9245 | 3.6180 | 2659 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 5 | WORK.ANA_DATA | 20.7216 | 3.6061 | 2650 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 6 | WORK.ANA_DATA | -5.8517 | 2.2498 | 5652 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 6 | WORK.ANA_DATA | -24.9581 | 3.6180 | 2659 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 6 | WORK.ANA_DATA | -14.8235 | 3.6061 | 2650 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 7 | WORK.ANA_DATA | 16.5578 | 2.2557 | 5654 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 7 | WORK.ANA_DATA | 1.0907 | 3.6359 | 2697 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 7 | WORK.ANA_DATA | 4.0510 | 3.6104 | 2660 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 8 | WORK.ANA_DATA | 59.3282 | 2.2620 | 5653 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 8 | WORK.ANA_DATA | 49.3858 | 3.6452 | 2717 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 8 | WORK.ANA_DATA | 33.5244 | 3.6235 | 2688 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 9 | WORK.ANA_DATA | 63.4943 | 2.2434 | 5652 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 9 | WORK.ANA_DATA | 59.9712 | 3.6129 | 2650 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 9 | WORK.ANA_DATA | 34.5374 | 3.6147 | 2669 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 4 | WORK.ANA_DATA | 7.9307 | 4.1864 | 2676 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 5 | WORK.ANA_DATA | 67.2822 | 3.6305 | 2685 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 5 | WORK.ANA_DATA | 50.8472 | 3.1957 | 5652 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 5 | WORK.ANA_DATA | 44.6442 | 4.1827 | 2669 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 6 | WORK.ANA_DATA | 18.0710 | 3.6337 | 2692 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 6 | WORK.ANA_DATA | -1.0355 | 3.1957 | 5652 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 6 | WORK.ANA_DATA | 9.0992 | 4.1827 | 2669 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 7 | WORK.ANA_DATA | 40.4804 | 3.6371 | 2699 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 7 | WORK.ANA_DATA | 25.0133 | 3.2146 | 5653 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 7 | WORK.ANA_DATA | 27.9737 | 4.1864 | 2676 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 8 | WORK.ANA_DATA | 83.2509 | 3.6417 | 2709 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 8 | WORK.ANA_DATA | 73.3085 | 3.2237 | 5652 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 8 | WORK.ANA_DATA | 57.4471 | 4.1977 | 2697 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 9 | WORK.ANA_DATA | 87.4170 | 3.6293 | 2683 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 9 | WORK.ANA_DATA | 83.8938 | 3.1925 | 5656 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 9 | WORK.ANA_DATA | 58.4601 | 4.1902 | 2683 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 5 | WORK.ANA_DATA | 59.3515 | 3.6093 | 2657 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 5 | WORK.ANA_DATA | 42.9165 | 4.1746 | 2655 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 5 | WORK.ANA_DATA | 36.7135 | 3.1671 | 5650 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 6 | WORK.ANA_DATA | 10.1403 | 3.6125 | 2664 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 6 | WORK.ANA_DATA | -8.9662 | 4.1746 | 2655 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 6 | WORK.ANA_DATA | 1.1684 | 3.1671 | 5650 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 7 | WORK.ANA_DATA | 32.5497 | 3.6159 | 2671 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 7 | WORK.ANA_DATA | 17.0826 | 4.1902 | 2683 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 7 | WORK.ANA_DATA | 20.0429 | 3.1720 | 5650 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 8 | WORK.ANA_DATA | 75.3202 | 3.6205 | 2681 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 8 | WORK.ANA_DATA | 65.3778 | 4.1982 | 2698 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 8 | WORK.ANA_DATA | 49.5164 | 3.1870 | 5652 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 9 | WORK.ANA_DATA | 79.4863 | 3.6080 | 2655 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 3 | 3 | 5 | 0.22 | 0.8254 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 6 | -7.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 6 | -10.78 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 6 | -11.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 7 | -0.96 | 0.3373 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 7 | -4.52 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 7 | -5.04 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 8 | 10.87 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 8 | 7.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 8 | 4.24 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 9 | 12.06 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 9 | 9.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 9 | 4.58 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 4 | -6.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 4 | -4.43 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 5 | 19.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 5 | 7.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 5 | 5.75 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 6 | -2.60 | 0.0093 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 6 | -6.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 6 | -4.11 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 7 | 7.34 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 7 | 0.30 | 0.7642 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 7 | 1.12 | 0.2619 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 8 | 26.23 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 8 | 13.55 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 8 | 9.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 9 | 28.30 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 9 | 16.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 9 | 9.55 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 4 | 1.89 | 0.0583 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 5 | 18.53 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 5 | 15.91 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 5 | 10.67 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 6 | 4.97 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 6 | -0.32 | 0.7459 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 6 | 2.18 | 0.0297 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 7 | 11.13 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 7 | 7.78 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 7 | 6.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 8 | 22.86 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 8 | 22.74 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 8 | 13.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 9 | 24.09 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 9 | 26.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 9 | 13.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 5 | 16.44 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 5 | 10.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 5 | 11.59 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 6 | 2.81 | 0.0050 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 6 | -2.15 | 0.0318 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 6 | 0.37 | 0.7122 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 7 | 9.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 7 | 4.08 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 7 | 6.32 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 8 | 20.80 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 8 | 15.57 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 8 | 15.54 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 9 | 22.03 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 3 | 3 | 5 | -5.5017 | 6.8968 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 6 | -32.9509 | -18.8005 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 6 | -53.1607 | -36.8036 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 6 | -41.0468 | -28.6483 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 7 | -10.5480 | 3.6156 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 7 | -27.1424 | -10.7243 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 7 | -22.1819 | -9.7642 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 8 | 32.2134 | 46.3950 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 8 | 21.1370 | 37.5866 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 8 | 7.2623 | 19.7385 |
| TRTPN (ATPTN) | 3 | 3 | 1 | 9 | 36.4039 | 50.5367 |
| TRTPN (ATPTN) | 3 | 3 | 2 | 9 | 31.7773 | 48.1170 |
| TRTPN (ATPTN) | 3 | 3 | 3 | 9 | 8.2948 | 20.7319 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 4 | -31.0438 | -16.8015 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 4 | -23.0714 | -8.9125 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 5 | 38.9584 | 47.7607 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 5 | 19.8302 | 34.0189 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 5 | 13.6505 | 27.7926 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 6 | -10.2622 | -1.4411 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 6 | -32.0525 | -17.8638 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 6 | -21.8945 | -7.7525 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 7 | 12.1358 | 20.9797 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 7 | -6.0389 | 8.2202 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 7 | -3.0285 | 11.1305 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 8 | 54.8938 | 63.7626 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 8 | 42.2382 | 56.5334 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 8 | 26.4193 | 40.6295 |
| TRTPN (ATPTN) | 1 | 4 | 1 | 9 | 59.0965 | 67.8922 |
| TRTPN (ATPTN) | 1 | 4 | 2 | 9 | 52.8869 | 67.0555 |
| TRTPN (ATPTN) | 1 | 4 | 3 | 9 | 27.4494 | 41.6254 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 4 | -0.2782 | 16.1396 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 5 | 60.1633 | 74.4011 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 5 | 44.5824 | 57.1119 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 5 | 36.4425 | 52.8460 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 6 | 10.9458 | 25.1962 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 6 | -7.3002 | 5.2293 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 6 | 0.8974 | 17.3009 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 7 | 33.3487 | 47.6122 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 7 | 18.7114 | 31.3153 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 7 | 19.7647 | 36.1827 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 8 | 76.1102 | 90.3916 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 8 | 66.9888 | 79.6281 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 8 | 49.2160 | 65.6782 |
| TRTPN (ATPTN) | 2 | 4 | 1 | 9 | 80.3006 | 94.5335 |
| TRTPN (ATPTN) | 2 | 4 | 2 | 9 | 77.6353 | 90.1524 |
| TRTPN (ATPTN) | 2 | 4 | 3 | 9 | 50.2438 | 66.6764 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 5 | 52.2743 | 66.4288 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 5 | 34.7307 | 51.1023 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 5 | 30.5047 | 42.9223 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 6 | 3.0567 | 17.2239 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 6 | -17.1520 | -0.7804 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 6 | -5.0404 | 7.3773 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 7 | 25.4596 | 39.6399 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 7 | 8.8663 | 25.2989 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 7 | 13.8245 | 26.2614 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 8 | 68.2210 | 82.4193 |
| TRTPN (ATPTN) | 3 | 4 | 2 | 8 | 57.1457 | 73.6098 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 8 | 43.2687 | 55.7640 |
| TRTPN (ATPTN) | 3 | 4 | 1 | 9 | 72.4115 | 86.5611 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 3 | 4 | 2 | 9 | WORK.ANA_DATA | 75.9631 | 4.1702 | 2648 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 9 | WORK.ANA_DATA | 50.5293 | 3.1770 | 5651 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 5 | WORK.ANA_DATA | -16.4351 | 3.6169 | 2657 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 5 | WORK.ANA_DATA | -22.6380 | 3.6050 | 2648 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 6 | WORK.ANA_DATA | -49.2112 | 2.2480 | 5651 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 6 | WORK.ANA_DATA | -68.3177 | 3.6169 | 2657 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 6 | WORK.ANA_DATA | -58.1831 | 3.6050 | 2648 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 7 | WORK.ANA_DATA | -26.8018 | 2.2529 | 5651 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 7 | WORK.ANA_DATA | -42.2689 | 3.6348 | 2695 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 7 | WORK.ANA_DATA | -39.3086 | 3.6093 | 2657 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 8 | WORK.ANA_DATA | 15.9686 | 2.2603 | 5653 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 8 | WORK.ANA_DATA | 6.0262 | 3.6441 | 2715 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 8 | WORK.ANA_DATA | -9.8352 | 3.6224 | 2685 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 9 | WORK.ANA_DATA | 20.1348 | 2.2422 | 5654 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 9 | WORK.ANA_DATA | 16.6116 | 3.6118 | 2648 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 9 | WORK.ANA_DATA | -8.8222 | 3.6136 | 2667 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 5 | WORK.ANA_DATA | -6.2030 | 4.1709 | 2648 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 6 | WORK.ANA_DATA | -32.7762 | 3.6201 | 2664 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 6 | WORK.ANA_DATA | -51.8827 | 3.1802 | 5649 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 6 | WORK.ANA_DATA | -41.7480 | 4.1709 | 2648 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 7 | WORK.ANA_DATA | -10.3667 | 3.6235 | 2671 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 7 | WORK.ANA_DATA | -25.8338 | 3.2006 | 5652 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 7 | WORK.ANA_DATA | -22.8735 | 4.1746 | 2655 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 8 | WORK.ANA_DATA | 32.4037 | 3.6280 | 2681 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 8 | WORK.ANA_DATA | 22.4613 | 3.2111 | 5654 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 8 | WORK.ANA_DATA | 6.5999 | 4.1860 | 2676 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 9 | WORK.ANA_DATA | 36.5698 | 3.6156 | 2655 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 9 | WORK.ANA_DATA | 33.0467 | 3.1770 | 5653 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 9 | WORK.ANA_DATA | 7.6129 | 4.1784 | 2662 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 6 | WORK.ANA_DATA | -26.5732 | 3.6082 | 2655 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 6 | WORK.ANA_DATA | -45.6797 | 4.1709 | 2648 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 6 | WORK.ANA_DATA | -35.5451 | 3.1623 | 5649 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 7 | WORK.ANA_DATA | -4.1638 | 3.6116 | 2662 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 7 | WORK.ANA_DATA | -19.6309 | 4.1865 | 2676 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 7 | WORK.ANA_DATA | -16.6706 | 3.1672 | 5650 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 8 | WORK.ANA_DATA | 38.6067 | 3.6162 | 2672 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 8 | WORK.ANA_DATA | 28.6643 | 4.1945 | 2691 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 8 | WORK.ANA_DATA | 12.8029 | 3.1821 | 5651 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 9 | WORK.ANA_DATA | 42.7728 | 3.6037 | 2646 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 9 | WORK.ANA_DATA | 39.2496 | 4.1664 | 2641 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 9 | WORK.ANA_DATA | 13.8158 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 6 | WORK.ANA_DATA | -19.1065 | 3.6201 | 2664 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 6 | WORK.ANA_DATA | -8.9718 | 3.6082 | 2655 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 7 | WORK.ANA_DATA | 22.4094 | 2.2586 | 5653 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 7 | WORK.ANA_DATA | 6.9423 | 3.6381 | 2702 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 7 | WORK.ANA_DATA | 9.9027 | 3.6125 | 2664 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 8 | WORK.ANA_DATA | 65.1799 | 2.2655 | 5654 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 8 | WORK.ANA_DATA | 55.2375 | 3.6473 | 2722 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 8 | WORK.ANA_DATA | 39.3761 | 3.6256 | 2692 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 9 | WORK.ANA_DATA | 69.3460 | 2.2474 | 5654 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 9 | WORK.ANA_DATA | 65.8228 | 3.6150 | 2655 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 9 | WORK.ANA_DATA | 40.3891 | 3.6169 | 2674 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 6 | WORK.ANA_DATA | 10.1346 | 4.1709 | 2648 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 7 | WORK.ANA_DATA | 41.5159 | 3.6235 | 2671 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 7 | WORK.ANA_DATA | 26.0488 | 3.2006 | 5652 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 7 | WORK.ANA_DATA | 29.0091 | 4.1746 | 2655 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 8 | WORK.ANA_DATA | 84.2864 | 3.6280 | 2681 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 8 | WORK.ANA_DATA | 74.3439 | 3.2111 | 5654 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 8 | WORK.ANA_DATA | 58.4826 | 4.1860 | 2676 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 3 | 4 | 2 | 9 | 18.22 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 9 | 15.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 5 | -4.54 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 5 | -6.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 6 | -21.89 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 6 | -18.89 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 6 | -16.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 7 | -11.90 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 7 | -11.63 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 7 | -10.89 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 8 | 7.06 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 8 | 1.65 | 0.0983 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 8 | -2.72 | 0.0067 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 9 | 8.98 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 9 | 4.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 9 | -2.44 | 0.0147 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 5 | -1.49 | 0.1371 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 6 | -9.05 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 6 | -16.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 6 | -10.01 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 7 | -2.86 | 0.0043 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 7 | -8.07 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 7 | -5.48 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 8 | 8.93 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 8 | 6.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 8 | 1.58 | 0.1150 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 9 | 10.11 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 9 | 10.40 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 9 | 1.82 | 0.0686 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 6 | -7.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 6 | -10.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 6 | -11.24 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 7 | -1.15 | 0.2491 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 7 | -4.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 7 | -5.26 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 8 | 10.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 8 | 6.83 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 8 | 4.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 9 | 11.87 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 9 | 9.42 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 9 | 4.36 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 6 | -5.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 6 | -2.49 | 0.0130 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 7 | 9.92 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 7 | 1.91 | 0.0565 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 7 | 2.74 | 0.0062 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 8 | 28.77 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 8 | 15.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 8 | 10.86 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 9 | 30.86 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 9 | 18.21 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 9 | 11.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 6 | 2.43 | 0.0152 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 7 | 11.46 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 7 | 8.14 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 7 | 6.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 8 | 23.23 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 8 | 23.15 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 8 | 13.97 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 4 | 2 | 9 | 67.7860 | 84.1402 |
| TRTPN (ATPTN) | 3 | 4 | 3 | 9 | 44.3012 | 56.7575 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 5 | -23.5272 | -9.3429 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 5 | -29.7069 | -15.5691 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 6 | -53.6182 | -44.8043 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 6 | -75.4099 | -61.2255 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 6 | -65.2520 | -51.1142 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 7 | -31.2183 | -22.3853 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 7 | -49.3963 | -35.1415 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 7 | -46.3859 | -32.2313 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 8 | 11.5377 | 20.3996 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 8 | -1.1192 | 13.1717 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 8 | -16.9381 | -2.7322 |
| TRTPN (ATPTN) | 1 | 5 | 1 | 9 | 15.7393 | 24.5303 |
| TRTPN (ATPTN) | 1 | 5 | 2 | 9 | 9.5295 | 23.6937 |
| TRTPN (ATPTN) | 1 | 5 | 3 | 9 | -15.9080 | -1.7364 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 5 | -14.3816 | 1.9757 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 6 | -39.8747 | -25.6777 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 6 | -58.1170 | -45.6483 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 6 | -49.9266 | -33.5695 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 7 | -17.4718 | -3.2617 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 7 | -32.1082 | -19.5595 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 7 | -31.0594 | -14.6877 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 8 | 25.2897 | 39.5177 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 8 | 16.1663 | 28.7562 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 8 | -1.6081 | 14.8079 |
| TRTPN (ATPTN) | 2 | 5 | 1 | 9 | 29.4801 | 43.6596 |
| TRTPN (ATPTN) | 2 | 5 | 2 | 9 | 26.8185 | 39.2748 |
| TRTPN (ATPTN) | 2 | 5 | 3 | 9 | -0.5803 | 15.8061 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 6 | -33.6484 | -19.4980 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 6 | -53.8583 | -37.5011 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 6 | -41.7443 | -29.3458 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 7 | -11.2456 | 2.9180 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 7 | -27.8400 | -11.4218 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 7 | -22.8794 | -10.4617 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 8 | 31.5159 | 45.6975 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 8 | 20.4394 | 36.8891 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 8 | 6.5648 | 19.0410 |
| TRTPN (ATPTN) | 3 | 5 | 1 | 9 | 35.7064 | 49.8392 |
| TRTPN (ATPTN) | 3 | 5 | 2 | 9 | 31.0798 | 47.4195 |
| TRTPN (ATPTN) | 3 | 5 | 3 | 9 | 7.5973 | 20.0344 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 6 | -26.2050 | -12.0080 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 6 | -16.0471 | -1.8966 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 7 | 17.9818 | 26.8371 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 7 | -0.1913 | 14.0760 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 7 | 2.8190 | 16.9863 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 8 | 60.7386 | 69.6212 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 8 | 48.0857 | 62.3892 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 8 | 32.2668 | 46.4853 |
| TRTPN (ATPTN) | 1 | 6 | 1 | 9 | 64.9403 | 73.7517 |
| TRTPN (ATPTN) | 1 | 6 | 2 | 9 | 58.7344 | 72.9113 |
| TRTPN (ATPTN) | 1 | 6 | 3 | 9 | 33.2969 | 47.4812 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 6 | 1.9560 | 18.3133 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 7 | 34.4109 | 48.6210 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 7 | 19.7744 | 32.3232 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 7 | 20.8233 | 37.1950 |
| TRTPN (ATPTN) | 2 | 6 | 1 | 8 | 77.1723 | 91.4004 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 8 | 68.0490 | 80.6389 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 8 | 50.2745 | 66.6906 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Margins | Estimate | Standard Error | DF |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------------|----------|----------------|------|
| TRTPN (ATPTN) | 2 | 6 | 1 | 9 | WORK.ANA_DATA | 88.4525 | 3.6156 | 2655 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 9 | WORK.ANA_DATA | 84.9293 | 3.1770 | 5653 |
| TRTPN (ATPTN) | 2 | 6 | 3 | 9 | WORK.ANA_DATA | 59.4955 | 4.1784 | 2662 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 7 | WORK.ANA_DATA | 31.3813 | 3.6116 | 2662 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 7 | WORK.ANA_DATA | 15.9142 | 4.1865 | 2676 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 7 | WORK.ANA_DATA | 18.8745 | 3.1672 | 5650 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 8 | WORK.ANA_DATA | 74.1517 | 3.6162 | 2672 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 8 | WORK.ANA_DATA | 64.2093 | 4.1945 | 2691 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 8 | WORK.ANA_DATA | 48.3479 | 3.1821 | 5651 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 9 | WORK.ANA_DATA | 78.3179 | 3.6037 | 2646 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 9 | WORK.ANA_DATA | 74.7947 | 4.1664 | 2641 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 9 | WORK.ANA_DATA | 49.3609 | 3.1721 | 5650 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 7 | WORK.ANA_DATA | -15.4671 | 3.6413 | 2709 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 7 | WORK.ANA_DATA | -12.5068 | 3.6159 | 2671 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 8 | WORK.ANA_DATA | 42.7704 | 2.2704 | 5654 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 8 | WORK.ANA_DATA | 32.8280 | 3.6506 | 2729 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 8 | WORK.ANA_DATA | 16.9666 | 3.6290 | 2700 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 9 | WORK.ANA_DATA | 46.9366 | 2.2528 | 5655 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 9 | WORK.ANA_DATA | 43.4134 | 3.6183 | 2662 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 9 | WORK.ANA_DATA | 17.9796 | 3.6202 | 2681 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 7 | WORK.ANA_DATA | 2.9603 | 4.1903 | 2683 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 8 | WORK.ANA_DATA | 58.2375 | 3.6460 | 2719 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 8 | WORK.ANA_DATA | 48.2951 | 3.2300 | 5654 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 8 | WORK.ANA_DATA | 32.4337 | 4.2015 | 2704 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 9 | WORK.ANA_DATA | 62.4037 | 3.6336 | 2693 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 9 | WORK.ANA_DATA | 58.8805 | 3.1974 | 5656 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 9 | WORK.ANA_DATA | 33.4467 | 4.1939 | 2690 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 8 | WORK.ANA_DATA | 55.2772 | 3.6205 | 2681 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 8 | WORK.ANA_DATA | 45.3348 | 4.1982 | 2698 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 8 | WORK.ANA_DATA | 29.4734 | 3.1870 | 5652 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 9 | WORK.ANA_DATA | 59.4433 | 3.6080 | 2655 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 9 | WORK.ANA_DATA | 55.9202 | 4.1702 | 2648 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 9 | WORK.ANA_DATA | 30.4864 | 3.1770 | 5651 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 8 | WORK.ANA_DATA | -9.9424 | 3.6551 | 2738 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 8 | WORK.ANA_DATA | -25.8038 | 3.6335 | 2709 |
| TRTPN (ATPTN) | 1 | 8 | 1 | 9 | WORK.ANA_DATA | 4.1661 | 2.2595 | 5655 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 9 | WORK.ANA_DATA | 0.6430 | 3.6229 | 2672 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 9 | WORK.ANA_DATA | -24.7908 | 3.6248 | 2690 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 8 | WORK.ANA_DATA | -15.8614 | 4.2095 | 2719 |
| TRTPN (ATPTN) | 2 | 8 | 1 | 9 | WORK.ANA_DATA | 14.1085 | 3.6428 | 2712 |
| TRTPN (ATPTN) | 2 | 8 | 2 | 9 | WORK.ANA_DATA | 10.5854 | 3.2079 | 5658 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 9 | WORK.ANA_DATA | -14.8484 | 4.2020 | 2705 |
| TRTPN (ATPTN) | 3 | 8 | 1 | 9 | WORK.ANA_DATA | 29.9699 | 3.6211 | 2683 |
| TRTPN (ATPTN) | 3 | 8 | 2 | 9 | WORK.ANA_DATA | 26.4468 | 4.1815 | 2669 |
| TRTPN (ATPTN) | 3 | 8 | 3 | 9 | WORK.ANA_DATA | 1.0130 | 3.1919 | 5652 |
| TRTPN (ATPTN) | 1 | 9 | 2 | 9 | WORK.ANA_DATA | -3.5232 | 3.6105 | 2646 |
| TRTPN (ATPTN) | 1 | 9 | 3 | 9 | WORK.ANA_DATA | -28.9569 | 3.6123 | 2664 |
| TRTPN (ATPTN) | 2 | 9 | 3 | 9 | WORK.ANA_DATA | -25.4338 | 4.1740 | 2655 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) | 2 | 6 | 1 | 9 | 24.46 | <.0001 | 0.05 |
| TRTPN (ATPTN) | 2 | 6 | 2 | 9 | 26.73 | <.0001 | 0.05 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | t Value | Pr > t | Alpha |
|-----------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|-------|
| TRTPN (ATPTN) 2 | 2 | 6 | 3 | 9 | 14.24 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 1 | 7 | 8.69 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 2 | 7 | 3.80 | 0.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 3 | 7 | 5.96 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 1 | 8 | 20.51 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 2 | 8 | 15.31 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 3 | 8 | 15.19 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 1 | 9 | 21.73 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 2 | 9 | 17.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 6 | 3 | 9 | 15.56 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 2 | 7 | -4.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 3 | 7 | -3.46 | 0.0006 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 1 | 8 | 18.84 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 2 | 8 | 8.99 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 3 | 8 | 4.68 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 1 | 9 | 20.84 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 2 | 9 | 12.00 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 7 | 3 | 9 | 4.97 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 7 | 3 | 7 | 0.71 | 0.4800 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 7 | 1 | 8 | 15.97 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 7 | 2 | 8 | 14.95 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 7 | 3 | 8 | 7.72 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 7 | 1 | 9 | 17.17 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 7 | 2 | 9 | 18.41 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 7 | 3 | 9 | 7.98 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 7 | 1 | 8 | 15.27 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 7 | 2 | 8 | 10.80 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 7 | 3 | 8 | 9.25 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 7 | 1 | 9 | 16.48 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 7 | 2 | 9 | 13.41 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 7 | 3 | 9 | 9.60 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 8 | 2 | 8 | -2.72 | 0.0066 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 8 | 3 | 8 | -7.10 | <.0001 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 8 | 1 | 9 | 1.84 | 0.0653 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 8 | 2 | 9 | 0.18 | 0.8592 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 8 | 3 | 9 | -6.84 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 8 | 3 | 8 | -3.77 | 0.0002 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 8 | 1 | 9 | 3.87 | 0.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 8 | 2 | 9 | 3.30 | 0.0010 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 8 | 3 | 9 | -3.53 | 0.0004 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 8 | 1 | 9 | 8.28 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 8 | 2 | 9 | 6.32 | <.0001 | 0.05 |
| TRTPN (ATPTN) 3 | 3 | 8 | 3 | 9 | 0.32 | 0.7510 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 9 | 2 | 9 | -0.98 | 0.3293 | 0.05 |
| TRTPN (ATPTN) 1 | 1 | 9 | 3 | 9 | -8.02 | <.0001 | 0.05 |
| TRTPN (ATPTN) 2 | 2 | 9 | 3 | 9 | -6.09 | <.0001 | 0.05 |

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|-----------------|-------------------------------------|------------------------|-------------------------------------|------------------------|---------|---------|
| TRTPN (ATPTN) 2 | 2 | 6 | 1 | 9 | 81.3628 | 95.5422 |
| TRTPN (ATPTN) 2 | 2 | 6 | 2 | 9 | 78.7012 | 91.1575 |
| TRTPN (ATPTN) 2 | 2 | 6 | 3 | 9 | 51.3024 | 67.6887 |
| TRTPN (ATPTN) 3 | 3 | 6 | 1 | 7 | 24.2995 | 38.4631 |

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Differences of Least Squares Means

| Effect | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Planned Treatment for Period 01 (N) | Analysis Timepoint (N) | Lower | Upper |
|---------------|-------------------------------------|------------------------|-------------------------------------|------------------------|----------|----------|
| TRTPN (ATPTN) | 3 | 6 | 2 | 7 | 7.7051 | 24.1233 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 7 | 12.6657 | 25.0834 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 8 | 67.0609 | 81.2425 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 8 | 55.9845 | 72.4341 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 8 | 42.1098 | 54.5860 |
| TRTPN (ATPTN) | 3 | 6 | 1 | 9 | 71.2515 | 85.3842 |
| TRTPN (ATPTN) | 3 | 6 | 2 | 9 | 66.6248 | 82.9645 |
| TRTPN (ATPTN) | 3 | 6 | 3 | 9 | 43.1423 | 55.5795 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 7 | -22.6072 | -8.3270 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 7 | -19.5970 | -5.4165 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 8 | 38.3195 | 47.2214 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 8 | 25.6698 | 39.9863 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 8 | 9.8508 | 24.0824 |
| TRTPN (ATPTN) | 1 | 7 | 1 | 9 | 42.5203 | 51.3529 |
| TRTPN (ATPTN) | 1 | 7 | 2 | 9 | 36.3184 | 50.5084 |
| TRTPN (ATPTN) | 1 | 7 | 3 | 9 | 10.8809 | 25.0783 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 7 | -5.2561 | 11.1768 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 8 | 51.0884 | 65.3867 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 8 | 41.9630 | 54.6272 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 8 | 24.1953 | 40.6722 |
| TRTPN (ATPTN) | 2 | 7 | 1 | 9 | 55.2788 | 69.5286 |
| TRTPN (ATPTN) | 2 | 7 | 2 | 9 | 52.6123 | 65.1487 |
| TRTPN (ATPTN) | 2 | 7 | 3 | 9 | 25.2231 | 41.6704 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 8 | 48.1780 | 62.3764 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 8 | 37.1027 | 53.5669 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 8 | 23.2257 | 35.7211 |
| TRTPN (ATPTN) | 3 | 7 | 1 | 9 | 52.3685 | 66.5182 |
| TRTPN (ATPTN) | 3 | 7 | 2 | 9 | 47.7431 | 64.0973 |
| TRTPN (ATPTN) | 3 | 7 | 3 | 9 | 24.2582 | 36.7146 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 8 | -17.1095 | -2.7753 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 8 | -32.9286 | -18.6790 |
| TRTPN (ATPTN) | 1 | 8 | 1 | 9 | -0.2635 | 8.5957 |
| TRTPN (ATPTN) | 1 | 8 | 2 | 9 | -6.4611 | 7.7470 |
| TRTPN (ATPTN) | 1 | 8 | 3 | 9 | -31.8985 | -17.6832 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 8 | -24.1155 | -7.6073 |
| TRTPN (ATPTN) | 2 | 8 | 1 | 9 | 6.9655 | 21.2516 |
| TRTPN (ATPTN) | 2 | 8 | 2 | 9 | 4.2966 | 16.8742 |
| TRTPN (ATPTN) | 2 | 8 | 3 | 9 | -23.0878 | -6.6090 |
| TRTPN (ATPTN) | 3 | 8 | 1 | 9 | 22.8695 | 37.0704 |
| TRTPN (ATPTN) | 3 | 8 | 2 | 9 | 18.2474 | 34.6461 |
| TRTPN (ATPTN) | 3 | 8 | 3 | 9 | -5.2444 | 7.2704 |
| TRTPN (ATPTN) | 1 | 9 | 2 | 9 | -10.6029 | 3.5566 |
| TRTPN (ATPTN) | 1 | 9 | 3 | 9 | -36.0402 | -21.8737 |
| TRTPN (ATPTN) | 2 | 9 | 3 | 9 | -33.6184 | -17.2492 |

20: Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PSMPGM

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 12 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2.2712 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2600.9 |
| AIC (Smaller is Better) | 2602.9 |
| AICC (Smaller is Better) | 2602.9 |
| BIC (Smaller is Better) | 2607.4 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 6.4453 | 0.3205 | 703 | 20.11 | <.0001 | 0.05 |
| trtpn | | 1 | -1.1247 | 0.1394 | 703 | -8.07 | <.0001 | 0.05 |
| trtpn | | 2 | -0.3415 | 0.1610 | 703 | -2.12 | 0.0342 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.5115 | 0.1210 | 703 | -4.23 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.2153 | 0.02875 | 703 | 7.49 | <.0001 | 0.05 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PSMPGM

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|----------|
| Intercept | | | 5.8160 | 7.0746 |
| trtpn | | 1 | -1.3983 | -0.8511 |
| trtpn | | 2 | -0.6575 | -0.02547 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.7490 | -0.2740 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.1589 | 0.2718 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 37.60 | <.0001 |
| PREOAD2 | 1 | 703 | 17.88 | <.0001 |
| BASE | 1 | 703 | 56.10 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 7.3919 | 0.07976 | 703 | 92.68 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 8.1751 | 0.1133 | 703 | 72.15 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 8.5166 | 0.1143 | 703 | 74.52 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 7.2353 | 7.5485 | 1622.74 | 1387.52 | 1897.83 |
| trtpn | LSMeans, IDeg | 7.9526 | 8.3975 | 3551.30 | 2843.02 | 4436.05 |
| trtpn | LSMeans, Lira | 8.2922 | 8.7410 | 4996.93 | 3992.62 | 6253.87 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.7832 | 0.1386 | 703 | -5.65 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -1.0552 | -0.5112 | 0.4569 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.3481 | 0.5998 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PSMPGM

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -1.1247 | 0.1394 | 703 | -8.07 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -1.3983 | -0.8511 | 0.3247 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.2470 | 0.4270 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9SMPGMU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 12 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 737.49 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 6672.1 |
| AIC (Smaller is Better) | 6674.1 |
| AICC (Smaller is Better) | 6674.1 |
| BIC (Smaller is Better) | 6678.6 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 116.14 | 5.7760 | 703 | 20.11 | <.0001 | 0.05 |
| trtpn | | 1 | -20.2673 | 2.5114 | 703 | -8.07 | <.0001 | 0.05 |
| trtpn | | 2 | -6.1540 | 2.9007 | 703 | -2.12 | 0.0342 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -9.2178 | 2.1799 | 703 | -4.23 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.2153 | 0.02875 | 703 | 7.49 | <.0001 | 0.05 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9SMPGMU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|----------|
| Intercept | | | 104.80 | 127.48 |
| trtpn | | 1 | -25.1980 | -15.3365 |
| trtpn | | 2 | -11.8490 | -0.4590 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -13.4977 | -4.9379 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.1589 | 0.2718 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 37.60 | <.0001 |
| PREOAD2 | 1 | 703 | 17.88 | <.0001 |
| BASE | 1 | 703 | 56.10 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 133.20 | 1.4373 | 703 | 92.68 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 147.31 | 2.0417 | 703 | 72.15 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 153.47 | 2.0594 | 703 | 74.52 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 130.38 | 136.02 | 7.058E57 | 4.199E56 | 1.186E59 |
| trtpn | LSMeans, IDeg | 143.31 | 151.32 | 9.506E63 | 1.726E62 | 5.234E65 |
| trtpn | LSMeans, Lira | 149.43 | 157.51 | 4.473E66 | 7.846E64 | 2.55E68 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -14.1133 | 2.4968 | 703 | -5.65 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | -19.0154 | -9.2112 | 7.425E-7 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 5.517E-9 | 0.000100 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9SMPGMU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -20.2673 | 2.5114 | 703 | -8.07 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|----------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | <.0001 | 0.05 | -25.1980 | -15.3365 | 1.578E-9 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 1.14E-11 | 2.185E-7 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PSMPGM

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 12 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2.2712 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2600.9 |
| AIC (Smaller is Better) | 2602.9 |
| AICC (Smaller is Better) | 2602.9 |
| BIC (Smaller is Better) | 2607.4 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 6.4453 | 0.3205 | 703 | 20.11 | <.0001 | 0.05 |
| trtpn | | 1 | -1.1247 | 0.1394 | 703 | -8.07 | <.0001 | 0.05 |
| trtpn | | 2 | -0.3415 | 0.1610 | 703 | -2.12 | 0.0342 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.5115 | 0.1210 | 703 | -4.23 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.7847 | 0.02875 | 703 | -27.29 | <.0001 | 0.05 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PSMPGM

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|----------|
| Intercept | | | 5.8160 | 7.0746 |
| trtpn | | 1 | -1.3983 | -0.8511 |
| trtpn | | 2 | -0.6575 | -0.02547 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.7490 | -0.2740 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.8411 | -0.7282 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 37.60 | <.0001 |
| PREOAD2 | 1 | 703 | 17.88 | <.0001 |
| BASE | 1 | 703 | 744.98 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -2.9990 | 0.07976 | 703 | -37.60 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -2.2158 | 0.1133 | 703 | -19.56 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -1.8743 | 0.1143 | 703 | -16.40 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -3.1556 | -2.8425 |
| trtpn | Change from baseline, IDeg | 0.05 | -2.4383 | -1.9934 |
| trtpn | Change from baseline, Lira | 0.05 | -2.0987 | -1.6500 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9SMPGMU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 12 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 737.49 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 6672.1 |
| AIC (Smaller is Better) | 6674.1 |
| AICC (Smaller is Better) | 6674.1 |
| BIC (Smaller is Better) | 6678.6 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 116.14 | 5.7760 | 703 | 20.11 | <.0001 | 0.05 |
| trtpn | | 1 | -20.2673 | 2.5114 | 703 | -8.07 | <.0001 | 0.05 |
| trtpn | | 2 | -6.1540 | 2.9007 | 703 | -2.12 | 0.0342 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -9.2178 | 2.1799 | 703 | -4.23 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.7847 | 0.02875 | 703 | -27.29 | <.0001 | 0.05 |

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9SMPGMU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|----------|
| Intercept | | | 104.80 | 127.48 |
| trtpn | | 1 | -25.1980 | -15.3365 |
| trtpn | | 2 | -11.8490 | -0.4590 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -13.4977 | -4.9379 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.8411 | -0.7282 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 37.60 | <.0001 |
| PREOAD2 | 1 | 703 | 17.88 | <.0001 |
| BASE | 1 | 703 | 744.98 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -54.0429 | 1.4373 | 703 | -37.60 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -39.9296 | 2.0417 | 703 | -19.56 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -33.7756 | 2.0594 | 703 | -16.40 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| trtpn | Change from baseline, IDegLira | 0.05 | -56.8648 | -51.2210 |
| trtpn | Change from baseline, IDeg | 0.05 | -43.9381 | -35.9210 |
| trtpn | Change from baseline, Lira | 0.05 | -37.8188 | -29.7323 |

21: Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIBU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 709 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 709 |
| Number of Observations Not Used | 9 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 1902.47 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 7349.6 |
| AIC (Smaller is Better) | 7351.6 |
| AICC (Smaller is Better) | 7351.6 |
| BIC (Smaller is Better) | 7356.1 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 50.3800 | 4.2937 | 704 | 11.73 | <.0001 | 0.05 |
| trtpn | | 1 | 5.6651 | 4.0320 | 704 | 1.41 | 0.1604 | 0.05 |
| trtpn | | 2 | 14.1118 | 4.6635 | 704 | 3.03 | 0.0026 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -10.8133 | 3.5012 | 704 | -3.09 | 0.0021 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1397 | 0.02911 | 704 | 4.80 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIBU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|---------|
| Intercept | | | 41.9500 | 58.8101 |
| trtpn | | 1 | -2.2510 | 13.5813 |
| trtpn | | 2 | 4.9558 | 23.2678 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -17.6874 | -3.9393 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.08260 | 0.1969 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 704 | 4.67 | 0.0096 |
| PREOAD2 | 1 | 704 | 9.54 | 0.0021 |
| BASE | 1 | 704 | 23.05 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 63.9851 | 2.3037 | 704 | 27.77 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 72.4317 | 3.2899 | 704 | 22.02 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 58.3200 | 3.3073 | 704 | 17.63 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 59.4621 | 68.5081 | 6.143E27 | 6.669E25 | 5.658E29 |
| trtpn | LSMeans, IDeg | 65.9725 | 78.8910 | 2.862E31 | 4.482E28 | 1.828E34 |
| trtpn | LSMeans, Lira | 51.8266 | 64.8133 | 2.128E25 | 3.221E22 | 1.406E28 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -8.4466 | 4.0189 | 704 | -2.10 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0359 | 0.05 | -16.3372 | -0.5561 | 0.000215 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 8.033E-8 | 0.5734 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIBU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 5.6651 | 4.0320 | 704 | 1.41 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.1604 | 0.05 | -2.2510 | 13.5813 | 288.63 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.1053 | 791207 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIEU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 707 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 707 |
| Number of Observations Not Used | 11 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2035.95 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 7376.4 |
| AIC (Smaller is Better) | 7378.4 |
| AICC (Smaller is Better) | 7378.4 |
| BIC (Smaller is Better) | 7382.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 28.2369 | 3.8281 | 702 | 7.38 | <.0001 | 0.05 |
| trtpn | | 1 | 13.7323 | 4.1645 | 702 | 3.30 | 0.0010 | 0.05 |
| trtpn | | 2 | 15.3706 | 4.7970 | 702 | 3.20 | 0.0014 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -2.5249 | 3.6263 | 702 | -0.70 | 0.4865 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1860 | 0.03057 | 702 | 6.08 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIEU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 20.7210 | 35.7529 |
| trtpn | | 1 | 5.5560 | 21.9086 |
| trtpn | | 2 | 5.9524 | 24.7888 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -9.6446 | 4.5948 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.1259 | 0.2460 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 702 | 6.70 | 0.0013 |
| PREOAD2 | 1 | 702 | 0.48 | 0.4865 |
| BASE | 1 | 702 | 37.00 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 49.6516 | 2.4018 | 702 | 20.67 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 51.2899 | 3.3822 | 702 | 15.16 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 35.9193 | 3.4016 | 702 | 10.56 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 44.9360 | 54.3671 | 3.659E21 | 3.277E19 | 4.087E23 |
| trtpn | LSMeans, IDeg | 44.6494 | 57.9303 | 1.883E22 | 2.46E19 | 1.442E25 |
| trtpn | LSMeans, Lira | 29.2407 | 42.5979 | 3.977E15 | 5.001E12 | 3.162E18 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -1.6383 | 4.1484 | 702 | -0.39 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.6930 | 0.05 | -9.7830 | 6.5065 | 0.1943 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.000056 | 669.48 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIEU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 13.7323 | 4.1645 | 702 | 3.30 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.0010 | 0.05 | 5.5560 | 21.9086 | 920162 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 258.79 | 3.2717E9 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGILU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 10 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2006.21 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 7376.7 |
| AIC (Smaller is Better) | 7378.7 |
| AICC (Smaller is Better) | 7378.7 |
| BIC (Smaller is Better) | 7383.2 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 31.7807 | 3.6382 | 703 | 8.74 | <.0001 | 0.05 |
| trtpn | | 1 | 6.7797 | 4.1349 | 703 | 1.64 | 0.1015 | 0.05 |
| trtpn | | 2 | 16.6127 | 4.7770 | 703 | 3.48 | 0.0005 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.7065 | 3.5950 | 703 | 0.47 | 0.6352 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1446 | 0.02759 | 703 | 5.24 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGILU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 24.6377 | 38.9237 |
| trtpn | | 1 | -1.3385 | 14.8979 |
| trtpn | | 2 | 7.2337 | 25.9916 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -5.3517 | 8.7648 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.09041 | 0.1987 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 6.15 | 0.0022 |
| PREOAD2 | 1 | 703 | 0.23 | 0.6352 |
| BASE | 1 | 703 | 27.46 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 44.9642 | 2.3828 | 703 | 18.87 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 54.7972 | 3.3775 | 703 | 16.22 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 38.1846 | 3.3702 | 703 | 11.33 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 40.2859 | 49.6426 | 3.371E19 | 3.133E17 | 3.627E21 |
| trtpn | LSMeans, IDeg | 48.1661 | 61.4284 | 6.283E23 | 8.284E20 | 4.765E26 |
| trtpn | LSMeans, Lira | 31.5677 | 44.8015 | 3.831E16 | 5.125E13 | 2.864E19 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -9.8330 | 4.1312 | 703 | -2.38 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0176 | 0.05 | -17.9439 | -1.7221 | 0.000054 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 1.611E-8 | 0.1787 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGILU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 6.7797 | 4.1349 | 703 | 1.64 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.1015 | 0.05 | -1.3385 | 14.8979 | 879.78 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.2622 | 2951642 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINC

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2.6091 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2736.5 |
| AIC (Smaller is Better) | 2738.5 |
| AICC (Smaller is Better) | 2738.5 |
| BIC (Smaller is Better) | 2743.1 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 2.0022 | 0.1527 | 713 | 13.12 | <.0001 | 0.05 |
| trtpn | | 1 | 0.4424 | 0.1479 | 713 | 2.99 | 0.0029 | 0.05 |
| trtpn | | 2 | 0.8538 | 0.1710 | 713 | 4.99 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.2348 | 0.1288 | 713 | -1.82 | 0.0688 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1750 | 0.02899 | 713 | 6.04 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINC

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 1.7025 | 2.3019 |
| trtpn | | 1 | 0.1521 | 0.7327 |
| trtpn | | 2 | 0.5180 | 1.1895 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.4876 | 0.01811 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.1181 | 0.2319 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 12.47 | <.0001 |
| PREOAD2 | 1 | 713 | 3.32 | 0.0688 |
| BASE | 1 | 713 | 36.43 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 2.9129 | 0.08514 | 713 | 34.21 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 3.3242 | 0.1208 | 713 | 27.52 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 2.4705 | 0.1209 | 713 | 20.44 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 2.7457 | 3.0800 | 18.4094 | 15.5757 | 21.7585 |
| trtpn | LSMeans, IDeg | 3.0871 | 3.5614 | 27.7781 | 21.9128 | 35.2134 |
| trtpn | LSMeans, Lira | 2.2332 | 2.7077 | 11.8280 | 9.3295 | 14.9955 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.4114 | 0.1478 | 713 | -2.78 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0055 | 0.05 | -0.7015 | -0.1213 | 0.6627 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.4958 | 0.8858 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINC

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 0.4424 | 0.1479 | 713 | 2.99 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.0029 | 0.05 | 0.1521 | 0.7327 | 1.5564 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 1.1643 | 2.0807 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCB

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 709 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 709 |
| Number of Observations Not Used | 9 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 5.8588 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3272.6 |
| AIC (Smaller is Better) | 3274.6 |
| AICC (Smaller is Better) | 3274.6 |
| BIC (Smaller is Better) | 3279.2 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 2.7958 | 0.2383 | 704 | 11.73 | <.0001 | 0.05 |
| trtpn | | 1 | 0.3144 | 0.2238 | 704 | 1.41 | 0.1604 | 0.05 |
| trtpn | | 2 | 0.7831 | 0.2588 | 704 | 3.03 | 0.0026 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.6001 | 0.1943 | 704 | -3.09 | 0.0021 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1397 | 0.02911 | 704 | 4.80 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCB

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 2.3280 | 3.2636 |
| trtpn | | 1 | -0.1249 | 0.7537 |
| trtpn | | 2 | 0.2750 | 1.2912 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.9815 | -0.2186 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.08260 | 0.1969 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 704 | 4.67 | 0.0096 |
| PREOAD2 | 1 | 704 | 9.54 | 0.0021 |
| BASE | 1 | 704 | 23.05 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 3.5508 | 0.1278 | 704 | 27.77 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 4.0195 | 0.1826 | 704 | 22.02 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 3.2364 | 0.1835 | 704 | 17.63 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 3.2998 | 3.8018 | 34.8406 | 27.1067 | 44.7809 |
| trtpn | LSMeans, IDeg | 3.6611 | 4.3780 | 55.6743 | 38.9029 | 79.6761 |
| trtpn | LSMeans, Lira | 2.8761 | 3.5967 | 25.4420 | 17.7442 | 36.4793 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.4687 | 0.2230 | 704 | -2.10 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|----------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0359 | 0.05 | -0.9066 | -0.03086 | 0.6258 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.4039 | 0.9696 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCB

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 0.3144 | 0.2238 | 704 | 1.41 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.1604 | 0.05 | -0.1249 | 0.7537 | 1.3694 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.8826 | 2.1248 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCE

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 707 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 707 |
| Number of Observations Not Used | 11 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 6.2699 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3311.0 |
| AIC (Smaller is Better) | 3313.0 |
| AICC (Smaller is Better) | 3313.0 |
| BIC (Smaller is Better) | 3317.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.5670 | 0.2124 | 702 | 7.38 | <.0001 | 0.05 |
| trtpn | | 1 | 0.7621 | 0.2311 | 702 | 3.30 | 0.0010 | 0.05 |
| trtpn | | 2 | 0.8530 | 0.2662 | 702 | 3.20 | 0.0014 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.1401 | 0.2012 | 702 | -0.70 | 0.4865 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1860 | 0.03057 | 702 | 6.08 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCE

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|--------|
| Intercept | | | 1.1499 | 1.9841 |
| trtpn | | 1 | 0.3083 | 1.2158 |
| trtpn | | 2 | 0.3303 | 1.3756 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5352 | 0.2550 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.1259 | 0.2460 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 702 | 6.70 | 0.0013 |
| PREOAD2 | 1 | 702 | 0.48 | 0.4865 |
| BASE | 1 | 702 | 37.00 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 2.7554 | 0.1333 | 702 | 20.67 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 2.8463 | 0.1877 | 702 | 15.16 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 1.9933 | 0.1888 | 702 | 10.56 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 2.4937 | 3.0170 | 15.7267 | 12.1057 | 20.4308 |
| trtpn | LSMeans, IDeg | 2.4778 | 3.2148 | 17.2235 | 11.9146 | 24.8978 |
| trtpn | LSMeans, Lira | 1.6227 | 2.3639 | 7.3397 | 5.0666 | 10.6326 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.09091 | 0.2302 | 702 | -0.39 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.6930 | 0.05 | -0.5429 | 0.3611 | 0.9131 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.5811 | 1.4349 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCE

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 0.7621 | 0.2311 | 702 | 3.30 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.0010 | 0.05 | 0.3083 | 1.2158 | 2.1427 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 1.3611 | 3.3730 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCL

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 10 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 6.1783 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3305.5 |
| AIC (Smaller is Better) | 3307.5 |
| AICC (Smaller is Better) | 3307.5 |
| BIC (Smaller is Better) | 3312.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.7636 | 0.2019 | 703 | 8.74 | <.0001 | 0.05 |
| trtpn | | 1 | 0.3762 | 0.2295 | 703 | 1.64 | 0.1015 | 0.05 |
| trtpn | | 2 | 0.9219 | 0.2651 | 703 | 3.48 | 0.0005 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.09470 | 0.1995 | 703 | 0.47 | 0.6352 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1446 | 0.02759 | 703 | 5.24 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCL

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|--------|
| Intercept | | | 1.3672 | 2.1600 |
| trtpn | | 1 | -0.07428 | 0.8267 |
| trtpn | | 2 | 0.4014 | 1.4424 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.2970 | 0.4864 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.09041 | 0.1987 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 6.15 | 0.0022 |
| PREOAD2 | 1 | 703 | 0.23 | 0.6352 |
| BASE | 1 | 703 | 27.46 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 2.4952 | 0.1322 | 703 | 18.87 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 3.0409 | 0.1874 | 703 | 16.22 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 2.1190 | 0.1870 | 703 | 11.33 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 2.2356 | 2.7549 | 12.1247 | 9.3523 | 15.7188 |
| trtpn | LSMeans, IDeg | 2.6729 | 3.4089 | 20.9243 | 14.4822 | 30.2320 |
| trtpn | LSMeans, Lira | 1.7518 | 2.4862 | 8.3229 | 5.7650 | 12.0156 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -0.5457 | 0.2293 | 703 | -2.38 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|----------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0176 | 0.05 | -0.9958 | -0.09557 | 0.5795 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.3694 | 0.9089 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCL

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 0.3762 | 0.2295 | 703 | 1.64 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.1015 | 0.05 | -0.07428 | 0.8267 | 1.4568 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.9284 | 2.2859 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 847.22 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 6865.6 |
| AIC (Smaller is Better) | 6867.6 |
| AICC (Smaller is Better) | 6867.6 |
| BIC (Smaller is Better) | 6872.1 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 36.0789 | 2.7508 | 713 | 13.12 | <.0001 | 0.05 |
| trtpn | | 1 | 7.9719 | 2.6645 | 713 | 2.99 | 0.0029 | 0.05 |
| trtpn | | 2 | 15.3852 | 3.0818 | 713 | 4.99 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.2304 | 2.3209 | 713 | -1.82 | 0.0688 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.1750 | 0.02899 | 713 | 6.04 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 30.6782 | 41.4796 |
| trtpn | | 1 | 2.7408 | 13.2031 |
| trtpn | | 2 | 9.3347 | 21.4356 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -8.7870 | 0.3263 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.1181 | 0.2319 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 12.47 | <.0001 |
| PREOAD2 | 1 | 713 | 3.32 | 0.0688 |
| BASE | 1 | 713 | 36.43 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 52.4897 | 1.5341 | 713 | 34.21 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 59.9030 | 2.1769 | 713 | 27.52 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 44.5178 | 2.1779 | 713 | 20.44 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 49.4777 | 55.5017 | 6.252E22 | 3.075E21 | 1.271E24 |
| trtpn | LSMeans, IDeg | 55.6290 | 64.1769 | 1.036E26 | 1.443E24 | 7.442E27 |
| trtpn | LSMeans, Lira | 40.2420 | 48.7936 | 2.157E19 | 2.998E17 | 1.552E21 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -7.4132 | 2.6629 | 713 | -2.78 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|----------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0055 | 0.05 | -12.6413 | -2.1852 | 0.000603 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 3.236E-6 | 0.1125 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 7.9719 | 2.6645 | 713 | 2.99 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.0029 | 0.05 | 2.7408 | 13.2031 | 2898.47 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 15.4998 | 542016 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIBU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 709 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 709 |
| Number of Observations Not Used | 9 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 1902.47 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 7349.6 |
| AIC (Smaller is Better) | 7351.6 |
| AICC (Smaller is Better) | 7351.6 |
| BIC (Smaller is Better) | 7356.1 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 50.3800 | 4.2937 | 704 | 11.73 | <.0001 | 0.05 |
| trtpn | | 1 | 5.6651 | 4.0320 | 704 | 1.41 | 0.1604 | 0.05 |
| trtpn | | 2 | 14.1118 | 4.6635 | 704 | 3.03 | 0.0026 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -10.8133 | 3.5012 | 704 | -3.09 | 0.0021 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8603 | 0.02911 | 704 | -29.56 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIBU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|---------|
| Intercept | | | 41.9500 | 58.8101 |
| trtpn | | 1 | -2.2510 | 13.5813 |
| trtpn | | 2 | 4.9558 | 23.2678 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -17.6874 | -3.9393 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.9174 | -0.8031 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 704 | 4.67 | 0.0096 |
| PREOAD2 | 1 | 704 | 9.54 | 0.0021 |
| BASE | 1 | 704 | 873.62 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -17.9360 | 2.3037 | 704 | -7.79 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -9.4894 | 3.2899 | 704 | -2.88 | 0.0040 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -23.6011 | 3.3073 | 704 | -7.14 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| trtpn | Change from baseline, IDegLira | 0.05 | -22.4590 | -13.4130 |
| trtpn | Change from baseline, IDeg | 0.05 | -15.9486 | -3.0301 |
| trtpn | Change from baseline, Lira | 0.05 | -30.0945 | -17.1078 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIEU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 707 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 707 |
| Number of Observations Not Used | 11 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2035.95 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 7376.4 |
| AIC (Smaller is Better) | 7378.4 |
| AICC (Smaller is Better) | 7378.4 |
| BIC (Smaller is Better) | 7382.9 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 28.2369 | 3.8281 | 702 | 7.38 | <.0001 | 0.05 |
| trtpn | | 1 | 13.7323 | 4.1645 | 702 | 3.30 | 0.0010 | 0.05 |
| trtpn | | 2 | 15.3706 | 4.7970 | 702 | 3.20 | 0.0014 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -2.5249 | 3.6263 | 702 | -0.70 | 0.4865 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8140 | 0.03057 | 702 | -26.62 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIEU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 20.7210 | 35.7529 |
| trtpn | | 1 | 5.5560 | 21.9086 |
| trtpn | | 2 | 5.9524 | 24.7888 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -9.6446 | 4.5948 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.8741 | -0.7540 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 702 | 6.70 | 0.0013 |
| PREOAD2 | 1 | 702 | 0.48 | 0.4865 |
| BASE | 1 | 702 | 708.88 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 3.9262 | 2.4018 | 702 | 1.63 | 0.1026 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 5.5644 | 3.3822 | 702 | 1.65 | 0.1004 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -9.8061 | 3.4016 | 702 | -2.88 | 0.0041 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.7894 | 8.6417 |
| trtpn | Change from baseline, IDeg | 0.05 | -1.0761 | 12.2049 |
| trtpn | Change from baseline, Lira | 0.05 | -16.4847 | -3.1275 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGILU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 10 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2006.21 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 7376.7 |
| AIC (Smaller is Better) | 7378.7 |
| AICC (Smaller is Better) | 7378.7 |
| BIC (Smaller is Better) | 7383.2 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 31.7807 | 3.6382 | 703 | 8.74 | <.0001 | 0.05 |
| trtpn | | 1 | 6.7797 | 4.1349 | 703 | 1.64 | 0.1015 | 0.05 |
| trtpn | | 2 | 16.6127 | 4.7770 | 703 | 3.48 | 0.0005 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 1.7065 | 3.5950 | 703 | 0.47 | 0.6352 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8554 | 0.02759 | 703 | -31.01 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGILU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 24.6377 | 38.9237 |
| trtpn | | 1 | -1.3385 | 14.8979 |
| trtpn | | 2 | 7.2337 | 25.9916 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -5.3517 | 8.7648 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.9096 | -0.8013 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 6.15 | 0.0022 |
| PREOAD2 | 1 | 703 | 0.23 | 0.6352 |
| BASE | 1 | 703 | 961.45 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 4.5032 | 2.3828 | 703 | 1.89 | 0.0592 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 14.3362 | 3.3775 | 703 | 4.24 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -2.2764 | 3.3702 | 703 | -0.68 | 0.4996 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.1751 | 9.1816 |
| trtpn | Change from baseline, IDeg | 0.05 | 7.7051 | 20.9674 |
| trtpn | Change from baseline, Lira | 0.05 | -8.8933 | 4.3405 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINC

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 2.6091 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 2736.5 |
| AIC (Smaller is Better) | 2738.5 |
| AICC (Smaller is Better) | 2738.5 |
| BIC (Smaller is Better) | 2743.1 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 2.0022 | 0.1527 | 713 | 13.12 | <.0001 | 0.05 |
| trtpn | | 1 | 0.4424 | 0.1479 | 713 | 2.99 | 0.0029 | 0.05 |
| trtpn | | 2 | 0.8538 | 0.1710 | 713 | 4.99 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.2348 | 0.1288 | 713 | -1.82 | 0.0688 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8250 | 0.02899 | 713 | -28.46 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINC

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 1.7025 | 2.3019 |
| trtpn | | 1 | 0.1521 | 0.7327 |
| trtpn | | 2 | 0.5180 | 1.1895 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.4876 | 0.01811 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.8819 | -0.7681 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 12.47 | <.0001 |
| PREOAD2 | 1 | 713 | 3.32 | 0.0688 |
| BASE | 1 | 713 | 809.82 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -0.1987 | 0.08514 | 713 | -2.33 | 0.0199 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 0.2127 | 0.1208 | 713 | 1.76 | 0.0787 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -0.6411 | 0.1209 | 713 | -5.30 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|----------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.3658 | -0.03153 |
| trtpn | Change from baseline, IDeg | 0.05 | -0.02447 | 0.4499 |
| trtpn | Change from baseline, Lira | 0.05 | -0.8784 | -0.4038 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCB

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 709 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 709 |
| Number of Observations Not Used | 9 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 5.8588 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3272.6 |
| AIC (Smaller is Better) | 3274.6 |
| AICC (Smaller is Better) | 3274.6 |
| BIC (Smaller is Better) | 3279.2 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 2.7958 | 0.2383 | 704 | 11.73 | <.0001 | 0.05 |
| trtpn | | 1 | 0.3144 | 0.2238 | 704 | 1.41 | 0.1604 | 0.05 |
| trtpn | | 2 | 0.7831 | 0.2588 | 704 | 3.03 | 0.0026 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.6001 | 0.1943 | 704 | -3.09 | 0.0021 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8603 | 0.02911 | 704 | -29.56 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCB

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 2.3280 | 3.2636 |
| trtpn | | 1 | -0.1249 | 0.7537 |
| trtpn | | 2 | 0.2750 | 1.2912 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.9815 | -0.2186 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.9174 | -0.8031 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 704 | 4.67 | 0.0096 |
| PREOAD2 | 1 | 704 | 9.54 | 0.0021 |
| BASE | 1 | 704 | 873.62 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -0.9953 | 0.1278 | 704 | -7.79 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -0.5266 | 0.1826 | 704 | -2.88 | 0.0040 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -1.3097 | 0.1835 | 704 | -7.14 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -1.2463 | -0.7443 |
| trtpn | Change from baseline, IDeg | 0.05 | -0.8851 | -0.1682 |
| trtpn | Change from baseline, Lira | 0.05 | -1.6701 | -0.9494 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCE

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 707 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 707 |
| Number of Observations Not Used | 11 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 6.2699 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3311.0 |
| AIC (Smaller is Better) | 3313.0 |
| AICC (Smaller is Better) | 3313.0 |
| BIC (Smaller is Better) | 3317.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.5670 | 0.2124 | 702 | 7.38 | <.0001 | 0.05 |
| trtpn | | 1 | 0.7621 | 0.2311 | 702 | 3.30 | 0.0010 | 0.05 |
| trtpn | | 2 | 0.8530 | 0.2662 | 702 | 3.20 | 0.0014 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.1401 | 0.2012 | 702 | -0.70 | 0.4865 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8140 | 0.03057 | 702 | -26.62 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCE

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 1.1499 | 1.9841 |
| trtpn | | 1 | 0.3083 | 1.2158 |
| trtpn | | 2 | 0.3303 | 1.3756 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.5352 | 0.2550 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.8741 | -0.7540 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 702 | 6.70 | 0.0013 |
| PREOAD2 | 1 | 702 | 0.48 | 0.4865 |
| BASE | 1 | 702 | 708.88 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 0.2179 | 0.1333 | 702 | 1.63 | 0.1026 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 0.3088 | 0.1877 | 702 | 1.65 | 0.1004 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -0.5442 | 0.1888 | 702 | -2.88 | 0.0041 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.04381 | 0.4796 |
| trtpn | Change from baseline, IDeg | 0.05 | -0.05972 | 0.6773 |
| trtpn | Change from baseline, Lira | 0.05 | -0.9148 | -0.1736 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCL

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 708 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 718 |
| Number of Observations Used | 708 |
| Number of Observations Not Used | 10 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 6.1783 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 3305.5 |
| AIC (Smaller is Better) | 3307.5 |
| AICC (Smaller is Better) | 3307.5 |
| BIC (Smaller is Better) | 3312.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.7636 | 0.2019 | 703 | 8.74 | <.0001 | 0.05 |
| trtpn | | 1 | 0.3762 | 0.2295 | 703 | 1.64 | 0.1015 | 0.05 |
| trtpn | | 2 | 0.9219 | 0.2651 | 703 | 3.48 | 0.0005 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.09470 | 0.1995 | 703 | 0.47 | 0.6352 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8554 | 0.02759 | 703 | -31.01 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGINCL

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|----------|---------|
| Intercept | | | 1.3672 | 2.1600 |
| trtpn | | 1 | -0.07428 | 0.8267 |
| trtpn | | 2 | 0.4014 | 1.4424 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.2970 | 0.4864 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.9096 | -0.8013 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 703 | 6.15 | 0.0022 |
| PREOAD2 | 1 | 703 | 0.23 | 0.6352 |
| BASE | 1 | 703 | 961.45 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 0.2499 | 0.1322 | 703 | 1.89 | 0.0592 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 0.7956 | 0.1874 | 703 | 4.24 | <.0001 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -0.1263 | 0.1870 | 703 | -0.68 | 0.4996 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|--------|
| trtpn | Change from baseline, IDegLira | 0.05 | -0.00972 | 0.5095 |
| trtpn | Change from baseline, IDeg | 0.05 | 0.4276 | 1.1636 |
| trtpn | Change from baseline, Lira | 0.05 | -0.4935 | 0.2409 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 847.22 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 6865.6 |
| AIC (Smaller is Better) | 6867.6 |
| AICC (Smaller is Better) | 6867.6 |
| BIC (Smaller is Better) | 6872.1 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 36.0789 | 2.7508 | 713 | 13.12 | <.0001 | 0.05 |
| trtpn | | 1 | 7.9719 | 2.6645 | 713 | 2.99 | 0.0029 | 0.05 |
| trtpn | | 2 | 15.3852 | 3.0818 | 713 | 4.99 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -4.2304 | 2.3209 | 713 | -1.82 | 0.0688 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.8250 | 0.02899 | 713 | -28.46 | <.0001 | 0.05 |

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=P9PGIU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 30.6782 | 41.4796 |
| trtpn | | 1 | 2.7408 | 13.2031 |
| trtpn | | 2 | 9.3347 | 21.4356 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -8.7870 | 0.3263 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.8819 | -0.7681 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 713 | 12.47 | <.0001 |
| PREOAD2 | 1 | 713 | 3.32 | 0.0688 |
| BASE | 1 | 713 | 809.82 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -3.5802 | 1.5341 | 713 | -2.33 | 0.0199 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | 3.8331 | 2.1769 | 713 | 1.76 | 0.0787 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -11.5521 | 2.1779 | 713 | -5.30 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|----------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -6.5921 | -0.5682 |
| trtpn | Change from baseline, IDeg | 0.05 | -0.4409 | 8.1070 |
| trtpn | Change from baseline, Lira | 0.05 | -15.8279 | -7.2763 |

22: Fasting insulin after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=INS_TO_S

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 690 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 690 |
| Number of Observations Not Used | 30 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.3923 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1329.8 |
| AIC (Smaller is Better) | 1331.8 |
| AICC (Smaller is Better) | 1331.8 |
| BIC (Smaller is Better) | 1336.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 0.7793 | 0.1511 | 685 | 5.16 | <.0001 | 0.05 |
| trtpn | | 1 | -0.6006 | 0.05867 | 685 | -10.24 | <.0001 | 0.05 |
| trtpn | | 2 | -0.8995 | 0.06772 | 685 | -13.28 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.1397 | 0.05082 | 685 | 2.75 | 0.0061 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.7857 | 0.03686 | 685 | 21.32 | <.0001 | 0.05 |

Fasting insulin after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=INS_TO_S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.7158 | -0.4854 |
| trtpn | | 2 | -1.0325 | -0.7666 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.03996 | 0.2395 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.7133 | 0.8581 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 685 | 92.97 | <.0001 |
| PREOAD2 | 1 | 685 | 7.56 | 0.0061 |
| base_log | 1 | 685 | 454.43 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 3.3323 | 0.03368 | 685 | 98.94 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 3.0334 | 0.04766 | 685 | 63.65 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 3.9329 | 0.04800 | 685 | 81.94 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 3.2662 | 3.3984 | 28.0031 | 26.2112 | 29.9174 |
| trtpn | LSMeans, IDeg | 2.9398 | 3.1270 | 20.7677 | 18.9125 | 22.8049 |
| trtpn | LSMeans, Lira | 3.8387 | 4.0272 | 51.0568 | 46.4650 | 56.1022 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.2989 | 0.05834 | 685 | 5.12 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|--------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | 0.1844 | 0.4135 | 1.3484 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 1.2025 | 1.5120 |

Fasting insulin after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=INS_TO_S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.6006 | 0.05867 | 685 | -10.24 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.7158 | -0.4854 | 0.5485 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.4888 | 0.6154 |

23: Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C74736S

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 717 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 717 |
| Number of Observations Not Used | 3 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.2604 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1088.9 |
| AIC (Smaller is Better) | 1090.9 |
| AICC (Smaller is Better) | 1090.9 |
| BIC (Smaller is Better) | 1095.4 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -0.1787 | 0.04809 | 712 | -3.72 | 0.0002 | 0.05 |
| trtpn | | 1 | -0.5435 | 0.04666 | 712 | -11.65 | <.0001 | 0.05 |
| trtpn | | 2 | -0.8717 | 0.05399 | 712 | -16.15 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.1591 | 0.04070 | 712 | 3.91 | 0.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.8438 | 0.04307 | 712 | 19.59 | <.0001 | 0.05 |

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C74736S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower Upper | |
|----------|--|---|-------------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.2731 | -0.08427 |
| trtpn | | 2 | -0.6351 | -0.4519 |
| trtpn | | 3 | -0.9777 | -0.7657 |
| PREOAD2 | Metformin | | 0.07922 | 0.2391 |
| PREOAD2 | Metformin + OAD | | 0.7592 | 0.9283 |
| base_log | | | | |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 712 | 134.44 | <.0001 |
| PREOAD2 | 1 | 712 | 15.28 | 0.0001 |
| base_log | 1 | 712 | 383.88 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | -1.1571 | 0.02694 | 712 | -42.95 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | -1.4853 | 0.03825 | 712 | -38.83 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | -0.6136 | 0.03808 | 712 | -16.12 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | -1.2100 | -1.1042 | 0.3144 | 0.2982 | 0.3315 |
| trtpn | LSMeans, IDeg | -1.5604 | -1.4102 | 0.2264 | 0.2100 | 0.2441 |
| trtpn | LSMeans, Lira | -0.6884 | -0.5389 | 0.5414 | 0.5024 | 0.5834 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.3282 | 0.04678 | 712 | 7.02 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|--------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | 0.2364 | 0.4200 | 1.3885 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 1.2666 | 1.5220 |

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C74736S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.5435 | 0.04666 | 712 | -11.65 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.6351 | -0.4519 | 0.5807 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.5299 | 0.6364 |

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=CPEPTI_U

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 717 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 717 |
| Number of Observations Not Used | 3 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.2604 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1088.9 |
| AIC (Smaller is Better) | 1090.9 |
| AICC (Smaller is Better) | 1090.9 |
| BIC (Smaller is Better) | 1095.4 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -0.00601 | 0.04562 | 712 | -0.13 | 0.8952 | 0.05 |
| trtpn | | 1 | -0.5435 | 0.04666 | 712 | -11.65 | <.0001 | 0.05 |
| trtpn | | 2 | -0.8717 | 0.05399 | 712 | -16.15 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.1591 | 0.04070 | 712 | 3.91 | 0.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.8438 | 0.04307 | 712 | 19.59 | <.0001 | 0.05 |

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=CPEPTI_U

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.6351 | -0.4519 |
| trtpn | | 2 | -0.9777 | -0.7657 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.07922 | 0.2391 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.7592 | 0.9283 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 712 | 134.44 | <.0001 |
| PREOAD2 | 1 | 712 | 15.28 | 0.0001 |
| base_log | 1 | 712 | 383.88 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | -0.05188 | 0.02694 | 712 | -1.93 | 0.0545 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | -0.3801 | 0.03825 | 712 | -9.94 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 0.4917 | 0.03808 | 712 | 12.91 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|----------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | -0.1048 | 0.001007 | 0.9494 | 0.9005 | 1.0010 |
| trtpn | LSMeans, IDeg | -0.4552 | -0.3050 | 0.6838 | 0.6343 | 0.7371 |
| trtpn | LSMeans, Lira | 0.4169 | 0.5664 | 1.6350 | 1.5172 | 1.7619 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.3282 | 0.04678 | 712 | 7.02 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|--------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | 0.2364 | 0.4200 | 1.3885 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 1.2666 | 1.5220 |

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=CPEPTI_U

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.5435 | 0.04666 | 712 | -11.65 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.6351 | -0.4519 | 0.5807 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.5299 | 0.6364 |

24: Fasting glucagon after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C74859P

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 716 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 716 |
| Number of Observations Not Used | 4 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.2508 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1061.4 |
| AIC (Smaller is Better) | 1063.4 |
| AICC (Smaller is Better) | 1063.4 |
| BIC (Smaller is Better) | 1068.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.8063 | 0.09730 | 711 | 18.56 | <.0001 | 0.05 |
| trtpn | | 1 | -0.03470 | 0.04578 | 711 | -0.76 | 0.4487 | 0.05 |
| trtpn | | 2 | 0.02292 | 0.05309 | 711 | 0.43 | 0.6661 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.06368 | 0.04004 | 711 | 1.59 | 0.1122 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.4190 | 0.02777 | 711 | 15.09 | <.0001 | 0.05 |

Fasting glucagon after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C74859P

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.1246 | 0.05519 |
| trtpn | | 2 | -0.08132 | 0.1272 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.01494 | 0.1423 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.3645 | 0.4736 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 711 | 0.85 | 0.4276 |
| PREOAD2 | 1 | 711 | 2.53 | 0.1122 |
| base_log | 1 | 711 | 227.65 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 3.1465 | 0.02643 | 711 | 119.04 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 3.2042 | 0.03766 | 711 | 85.08 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 3.1812 | 0.03737 | 711 | 85.13 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 3.0946 | 3.1984 | 23.2554 | 22.0793 | 24.4942 |
| trtpn | LSMeans, IDeg | 3.1302 | 3.2781 | 24.6348 | 22.8790 | 26.5253 |
| trtpn | LSMeans, Lira | 3.1079 | 3.2546 | 24.0766 | 22.3734 | 25.9094 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | -0.05762 | 0.04601 | 711 | -1.25 | 0.2108 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.1479 | 0.03270 | 0.9440 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.8625 | 1.0332 |

Fasting glucagon after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C74859P

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.03470 | 0.04578 | 711 | -0.76 | 0.4487 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1246 | 0.05519 | 0.9659 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.8829 | 1.0567 |

25: HOMA-B after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=HOMA_BCS

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 690 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 690 |
| Number of Observations Not Used | 30 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.3530 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1257.7 |
| AIC (Smaller is Better) | 1259.7 |
| AICC (Smaller is Better) | 1259.7 |
| BIC (Smaller is Better) | 1264.2 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.9156 | 0.1653 | 685 | 11.59 | <.0001 | 0.05 |
| trtpn | | 1 | -0.02107 | 0.05561 | 685 | -0.38 | 0.7049 | 0.05 |
| trtpn | | 2 | -0.3761 | 0.06411 | 685 | -5.87 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.2495 | 0.04821 | 685 | 5.18 | <.0001 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6704 | 0.03092 | 685 | 21.68 | <.0001 | 0.05 |

HOMA-B after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=HOMA_BCS

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.1303 | 0.08811 |
| trtpn | | 2 | -0.5020 | -0.2503 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.1549 | 0.3442 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.6097 | 0.7311 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 685 | 24.13 | <.0001 |
| PREOAD2 | 1 | 685 | 26.79 | <.0001 |
| base_log | 1 | 685 | 470.21 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 5.4547 | 0.03195 | 685 | 170.72 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 5.0996 | 0.04518 | 685 | 112.88 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 5.4757 | 0.04548 | 685 | 120.41 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 5.3919 | 5.5174 | 233.85 | 219.63 | 248.99 |
| trtpn | LSMeans, IDeg | 5.0109 | 5.1883 | 163.96 | 150.04 | 179.16 |
| trtpn | LSMeans, Lira | 5.3865 | 5.5650 | 238.83 | 218.43 | 261.13 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.3551 | 0.05533 | 685 | 6.42 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|--------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | 0.2464 | 0.4637 | 1.4263 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 1.2795 | 1.5900 |

HOMA-B after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=HOMA_BCS

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.02107 | 0.05561 | 685 | -0.38 | 0.7049 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1303 | 0.08811 | 0.9791 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.8779 | 1.0921 |

26: HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105587S

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.02087 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | -710.3 |
| AIC (Smaller is Better) | -708.3 |
| AICC (Smaller is Better) | -708.3 |
| BIC (Smaller is Better) | -703.8 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 0.04221 | 0.01193 | 713 | 3.54 | 0.0004 | 0.05 |
| trtpn | | 1 | -0.00377 | 0.01320 | 713 | -0.29 | 0.7751 | 0.05 |
| trtpn | | 2 | 0.006356 | 0.01529 | 713 | 0.42 | 0.6777 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.03054 | 0.01155 | 713 | -2.64 | 0.0084 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.8509 | 0.02184 | 713 | 38.97 | <.0001 | 0.05 |

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105587S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.02970 | 0.02215 |
| trtpn | | 2 | -0.02365 | 0.03637 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.05321 | -0.00787 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.8080 | 0.8937 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 0.29 | 0.7458 |
| PREOAD2 | 1 | 713 | 7.00 | 0.0084 |
| base_log | 1 | 713 | 1518.36 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 0.1331 | 0.007616 | 713 | 17.47 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 0.1432 | 0.01083 | 713 | 13.22 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 0.1368 | 0.01078 | 713 | 12.69 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 0.1181 | 0.1480 | 1.1423 | 1.1254 | 1.1595 |
| trtpn | LSMeans, IDeg | 0.1219 | 0.1644 | 1.1539 | 1.1297 | 1.1787 |
| trtpn | LSMeans, Lira | 0.1157 | 0.1580 | 1.1466 | 1.1226 | 1.1712 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | -0.01013 | 0.01324 | 713 | -0.77 | 0.4444 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.03612 | 0.01586 | 0.9899 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9645 | 1.0160 |

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105587S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.00377 | 0.01320 | 713 | -0.29 | 0.7751 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.02970 | 0.02215 | 0.9962 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.9707 | 1.0224 |

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=HDL_SU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.02087 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | -710.3 |
| AIC (Smaller is Better) | -708.3 |
| AICC (Smaller is Better) | -708.3 |
| BIC (Smaller is Better) | -703.8 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 0.5871 | 0.08405 | 713 | 6.99 | <.0001 | 0.05 |
| trtpn | | 1 | -0.00377 | 0.01320 | 713 | -0.29 | 0.7751 | 0.05 |
| trtpn | | 2 | 0.006356 | 0.01529 | 713 | 0.42 | 0.6777 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.03054 | 0.01155 | 713 | -2.64 | 0.0084 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.8509 | 0.02184 | 713 | 38.97 | <.0001 | 0.05 |

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=HDL_SU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.02970 | 0.02215 |
| trtpn | | 2 | -0.02365 | 0.03637 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.05321 | -0.00787 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.8080 | 0.8937 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 0.29 | 0.7458 |
| PREOAD2 | 1 | 713 | 7.00 | 0.0084 |
| base_log | 1 | 713 | 1518.36 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 3.7866 | 0.007616 | 713 | 497.19 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 3.7967 | 0.01083 | 713 | 350.56 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 3.7903 | 0.01078 | 713 | 351.64 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 3.7716 | 3.8015 | 44.1045 | 43.4500 | 44.7690 |
| trtpn | LSMeans, IDeg | 3.7754 | 3.8180 | 44.5536 | 43.6163 | 45.5111 |
| trtpn | LSMeans, Lira | 3.7692 | 3.8115 | 44.2713 | 43.3443 | 45.2182 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | -0.01013 | 0.01324 | 713 | -0.77 | 0.4444 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.03612 | 0.01586 | 0.9899 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9645 | 1.0160 |

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=HDL_SU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.00377 | 0.01320 | 713 | -0.29 | 0.7751 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.02970 | 0.02215 | 0.9962 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.9707 | 1.0224 |

27: LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105588S

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 717 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 717 |
| Number of Observations Not Used | 3 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.09670 |

Fit Statistics

| | |
|--------------------------|-------|
| -2 Res Log Likelihood | 383.1 |
| AIC (Smaller is Better) | 385.1 |
| AICC (Smaller is Better) | 385.1 |
| BIC (Smaller is Better) | 389.7 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 0.2751 | 0.03638 | 712 | 7.56 | <.0001 | 0.05 |
| trtpn | | 1 | -0.04478 | 0.02840 | 712 | -1.58 | 0.1153 | 0.05 |
| trtpn | | 2 | 0.01832 | 0.03293 | 712 | 0.56 | 0.5783 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.001663 | 0.02477 | 712 | 0.07 | 0.9465 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6341 | 0.03134 | 712 | 20.24 | <.0001 | 0.05 |

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105588S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.1005 | 0.01098 |
| trtpn | | 2 | -0.04634 | 0.08297 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.04697 | 0.05030 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.5726 | 0.6956 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 712 | 2.84 | 0.0593 |
| PREOAD2 | 1 | 712 | 0.00 | 0.9465 |
| base_log | 1 | 712 | 409.47 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 0.7677 | 0.01642 | 712 | 46.75 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 0.8308 | 0.02336 | 712 | 35.57 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 0.8125 | 0.02318 | 712 | 35.05 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 0.7354 | 0.7999 | 2.1548 | 2.0864 | 2.2254 |
| trtpn | LSMeans, IDeg | 0.7849 | 0.8766 | 2.2951 | 2.1922 | 2.4028 |
| trtpn | LSMeans, Lira | 0.7669 | 0.8580 | 2.2534 | 2.1532 | 2.3584 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | -0.06309 | 0.02858 | 712 | -2.21 | 0.0276 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|----------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.1192 | -0.00698 | 0.9389 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.8876 | 0.9930 |

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105588S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.04478 | 0.02840 | 712 | -1.58 | 0.1153 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1005 | 0.01098 | 0.9562 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.9044 | 1.0110 |

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=LDL_SU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 717 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 717 |
| Number of Observations Not Used | 3 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.09670 |

Fit Statistics

| | |
|--------------------------|-------|
| -2 Res Log Likelihood | 383.1 |
| AIC (Smaller is Better) | 385.1 |
| AICC (Smaller is Better) | 385.1 |
| BIC (Smaller is Better) | 389.7 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.6119 | 0.1434 | 712 | 11.24 | <.0001 | 0.05 |
| trtpn | | 1 | -0.04478 | 0.02840 | 712 | -1.58 | 0.1153 | 0.05 |
| trtpn | | 2 | 0.01832 | 0.03293 | 712 | 0.56 | 0.5783 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.001663 | 0.02477 | 712 | 0.07 | 0.9465 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6341 | 0.03134 | 712 | 20.24 | <.0001 | 0.05 |

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=LDL_SU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.1005 | 0.01098 |
| trtpn | | 2 | -0.04634 | 0.08297 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.04697 | 0.05030 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.5726 | 0.6956 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 712 | 2.84 | 0.0593 |
| PREOAD2 | 1 | 712 | 0.00 | 0.9465 |
| base_log | 1 | 712 | 409.47 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 4.4212 | 0.01642 | 712 | 269.25 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 4.4843 | 0.02336 | 712 | 191.97 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 4.4660 | 0.02318 | 712 | 192.65 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 4.3889 | 4.4534 | 83.1951 | 80.5558 | 85.9209 |
| trtpn | LSMeans, IDeg | 4.4384 | 4.5301 | 88.6134 | 84.6413 | 92.7718 |
| trtpn | LSMeans, Lira | 4.4205 | 4.5115 | 87.0051 | 83.1340 | 91.0566 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | -0.06309 | 0.02858 | 712 | -2.21 | 0.0276 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|----------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.1192 | -0.00698 | 0.9389 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.8876 | 0.9930 |

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=LDL_SU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.04478 | 0.02840 | 712 | -1.58 | 0.1153 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1005 | 0.01098 | 0.9562 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.9044 | 1.0110 |

28: VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105589S

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.1590 |

Fit Statistics

| | |
|--------------------------|-------|
| -2 Res Log Likelihood | 739.1 |
| AIC (Smaller is Better) | 741.1 |
| AICC (Smaller is Better) | 741.1 |
| BIC (Smaller is Better) | 745.6 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -0.1589 | 0.03205 | 713 | -4.96 | <.0001 | 0.05 |
| trtpn | | 1 | -0.05191 | 0.03644 | 713 | -1.42 | 0.1547 | 0.05 |
| trtpn | | 2 | -0.1175 | 0.04219 | 713 | -2.79 | 0.0055 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.07176 | 0.03185 | 713 | 2.25 | 0.0246 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6564 | 0.02753 | 713 | 23.84 | <.0001 | 0.05 |

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105589S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.1235 | 0.01963 |
| trtpn | | 2 | -0.2003 | -0.03468 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.009229 | 0.1343 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.6024 | 0.7105 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 3.90 | 0.0206 |
| PREOAD2 | 1 | 713 | 5.08 | 0.0246 |
| base_log | 1 | 713 | 568.38 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | -0.3405 | 0.02102 | 713 | -16.20 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | -0.4061 | 0.02989 | 713 | -13.58 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | -0.2885 | 0.02975 | 713 | -9.70 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | -0.3817 | -0.2992 | 0.7114 | 0.6827 | 0.7414 |
| trtpn | LSMeans, IDeg | -0.4647 | -0.3474 | 0.6663 | 0.6283 | 0.7065 |
| trtpn | LSMeans, Lira | -0.3470 | -0.2301 | 0.7493 | 0.7068 | 0.7944 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.06560 | 0.03654 | 713 | 1.80 | 0.0730 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.00614 | 0.1373 | 1.0678 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9939 | 1.1472 |

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105589S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.05191 | 0.03644 | 713 | -1.42 | 0.1547 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1235 | 0.01963 | 0.9494 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.8839 | 1.0198 |

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=VLDL_SU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.1590 |

Fit Statistics

| | |
|--------------------------|-------|
| -2 Res Log Likelihood | 739.1 |
| AIC (Smaller is Better) | 741.1 |
| AICC (Smaller is Better) | 741.1 |
| BIC (Smaller is Better) | 745.6 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.0964 | 0.09974 | 713 | 10.99 | <.0001 | 0.05 |
| trtpn | | 1 | -0.05191 | 0.03644 | 713 | -1.42 | 0.1547 | 0.05 |
| trtpn | | 2 | -0.1175 | 0.04219 | 713 | -2.79 | 0.0055 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.07176 | 0.03185 | 713 | 2.25 | 0.0246 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6564 | 0.02753 | 713 | 23.84 | <.0001 | 0.05 |

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=VLDL_SU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.1235 | 0.01963 |
| trtpn | | 2 | -0.2003 | -0.03468 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.009229 | 0.1343 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.6024 | 0.7105 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 3.90 | 0.0206 |
| PREOAD2 | 1 | 713 | 5.08 | 0.0246 |
| base_log | 1 | 713 | 568.38 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 3.3131 | 0.02102 | 713 | 157.61 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 3.2475 | 0.02989 | 713 | 108.63 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 3.3650 | 0.02975 | 713 | 113.11 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 3.2718 | 3.3543 | 27.4688 | 26.3583 | 28.6262 |
| trtpn | LSMeans, IDeg | 3.1888 | 3.3061 | 25.7247 | 24.2584 | 27.2797 |
| trtpn | LSMeans, Lira | 3.3066 | 3.4234 | 28.9324 | 27.2909 | 30.6726 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.06560 | 0.03654 | 713 | 1.80 | 0.0730 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.00614 | 0.1373 | 1.0678 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9939 | 1.1472 |

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=VLDL_SU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.05191 | 0.03644 | 713 | -1.42 | 0.1547 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1235 | 0.01963 | 0.9494 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.8839 | 1.0198 |

29: Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C64812S

The Mixed Procedure

Model Information

Data Set WORK.ADATA2
 Dependent Variable aval_log
 Covariance Structure Diagonal
 Estimation Method REML
 Residual Variance Method Profile
 Fixed Effects SE Method Model-Based
 Degrees of Freedom Method Residual

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

Covariance Parameters 1
 Columns in X 7
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 718

Number of Observations

Number of Observations Read 720
 Number of Observations Used 718
 Number of Observations Not Used 2

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.1843 |

Fit Statistics

-2 Res Log Likelihood 844.6
 AIC (Smaller is Better) 846.6
 AICC (Smaller is Better) 846.6
 BIC (Smaller is Better) 851.2

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 0.1162 | 0.03729 | 713 | 3.12 | 0.0019 | 0.05 |
| trtpn | | 1 | -0.05449 | 0.03922 | 713 | -1.39 | 0.1652 | 0.05 |
| trtpn | | 2 | -0.1254 | 0.04541 | 713 | -2.76 | 0.0059 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.07324 | 0.03435 | 713 | 2.13 | 0.0333 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6416 | 0.02615 | 713 | 24.54 | <.0001 | 0.05 |

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C64812S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.1315 | 0.02252 |
| trtpn | | 2 | -0.2145 | -0.03622 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.005797 | 0.1407 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.5902 | 0.6929 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 3.84 | 0.0219 |
| PREOAD2 | 1 | 713 | 4.55 | 0.0333 |
| base_log | 1 | 713 | 601.98 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 0.4647 | 0.02263 | 713 | 20.53 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 0.3938 | 0.03218 | 713 | 12.24 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 0.5191 | 0.03202 | 713 | 16.21 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 0.4202 | 0.5091 | 1.5915 | 1.5223 | 1.6638 |
| trtpn | LSMeans, IDeg | 0.3306 | 0.4570 | 1.4826 | 1.3918 | 1.5793 |
| trtpn | LSMeans, Lira | 0.4563 | 0.5820 | 1.6806 | 1.5782 | 1.7896 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.07089 | 0.03934 | 713 | 1.80 | 0.0720 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.00635 | 0.1481 | 1.0735 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9937 | 1.1597 |

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C64812S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.05449 | 0.03922 | 713 | -1.39 | 0.1652 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1315 | 0.02252 | 0.9470 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.8768 | 1.0228 |

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=TRIG_SU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.1843 |

Fit Statistics

| | |
|--------------------------|-------|
| -2 Res Log Likelihood | 844.6 |
| AIC (Smaller is Better) | 846.6 |
| AICC (Smaller is Better) | 846.6 |
| BIC (Smaller is Better) | 851.2 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.7251 | 0.1372 | 713 | 12.58 | <.0001 | 0.05 |
| trtpn | | 1 | -0.05449 | 0.03922 | 713 | -1.39 | 0.1652 | 0.05 |
| trtpn | | 2 | -0.1254 | 0.04541 | 713 | -2.76 | 0.0059 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.07324 | 0.03435 | 713 | 2.13 | 0.0333 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6416 | 0.02615 | 713 | 24.54 | <.0001 | 0.05 |

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=TRIG_SU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.1315 | 0.02252 |
| trtpn | | 2 | -0.2145 | -0.03622 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | 0.005797 | 0.1407 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.5902 | 0.6929 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 3.84 | 0.0219 |
| PREOAD2 | 1 | 713 | 4.55 | 0.0333 |
| base_log | 1 | 713 | 601.98 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 4.9533 | 0.02263 | 713 | 218.87 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 4.8824 | 0.03218 | 713 | 151.71 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 5.0078 | 0.03202 | 713 | 156.38 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 4.9089 | 4.9977 | 141.64 | 135.49 | 148.08 |
| trtpn | LSMeans, IDeg | 4.8192 | 4.9456 | 131.95 | 123.87 | 140.55 |
| trtpn | LSMeans, Lira | 4.9449 | 5.0707 | 149.57 | 140.46 | 159.28 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.07089 | 0.03934 | 713 | 1.80 | 0.0720 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.00635 | 0.1481 | 1.0735 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9937 | 1.1597 |

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=TRIG_SU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.05449 | 0.03922 | 713 | -1.39 | 0.1652 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.1315 | 0.02252 | 0.9470 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.8768 | 1.0228 |

30: Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105586S

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.02679 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | -532.6 |
| AIC (Smaller is Better) | -530.6 |
| AICC (Smaller is Better) | -530.6 |
| BIC (Smaller is Better) | -526.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 0.4849 | 0.04556 | 713 | 10.64 | <.0001 | 0.05 |
| trtpn | | 1 | -0.03161 | 0.01495 | 713 | -2.11 | 0.0348 | 0.05 |
| trtpn | | 2 | 0.003833 | 0.01736 | 713 | 0.22 | 0.8253 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.01028 | 0.01304 | 713 | 0.79 | 0.4307 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6563 | 0.02899 | 713 | 22.64 | <.0001 | 0.05 |

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105586S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.06095 | -0.00226 |
| trtpn | | 2 | -0.03025 | 0.03791 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.01533 | 0.03590 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.5994 | 0.7133 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 3.78 | 0.0232 |
| PREOAD2 | 1 | 713 | 0.62 | 0.4307 |
| base_log | 1 | 713 | 512.47 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 1.4372 | 0.008628 | 713 | 166.58 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 1.4727 | 0.01230 | 713 | 119.76 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 1.4688 | 0.01221 | 713 | 120.27 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 1.4203 | 1.4542 | 4.2090 | 4.1383 | 4.2809 |
| trtpn | LSMeans, IDeg | 1.4485 | 1.4968 | 4.3609 | 4.2569 | 4.4674 |
| trtpn | LSMeans, Lira | 1.4449 | 1.4928 | 4.3442 | 4.2413 | 4.4496 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | -0.03544 | 0.01503 | 713 | -2.36 | 0.0186 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|----------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.06495 | -0.00593 | 0.9652 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9371 | 0.9941 |

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105586S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.03161 | 0.01495 | 713 | -2.11 | 0.0348 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|----------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.06095 | -0.00226 | 0.9689 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.9409 | 0.9977 |

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=T_CHOL_U

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 718 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 718 |
| Number of Observations Not Used | 2 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.02679 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | -532.6 |
| AIC (Smaller is Better) | -530.6 |
| AICC (Smaller is Better) | -530.6 |
| BIC (Smaller is Better) | -526.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.7405 | 0.1502 | 713 | 11.59 | <.0001 | 0.05 |
| trtpn | | 1 | -0.03161 | 0.01495 | 713 | -2.11 | 0.0348 | 0.05 |
| trtpn | | 2 | 0.003833 | 0.01736 | 713 | 0.22 | 0.8253 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.01028 | 0.01304 | 713 | 0.79 | 0.4307 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.6563 | 0.02899 | 713 | 22.64 | <.0001 | 0.05 |

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=T_CHOL_U

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|----------|
| | | | Intercept | |
| trtpn | | 1 | -0.06095 | -0.00226 |
| trtpn | | 2 | -0.03025 | 0.03791 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.01533 | 0.03590 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.5994 | 0.7133 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 713 | 3.78 | 0.0232 |
| PREOAD2 | 1 | 713 | 0.62 | 0.4307 |
| base_log | 1 | 713 | 512.47 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 5.0907 | 0.008628 | 713 | 590.03 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 5.1262 | 0.01230 | 713 | 416.87 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 5.1224 | 0.01221 | 713 | 419.42 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 5.0738 | 5.1077 | 162.51 | 159.78 |
| trtpn | LSMeans, IDeg | 5.1020 | 5.1503 | 168.37 | 164.36 |
| trtpn | LSMeans, Lira | 5.0984 | 5.1463 | 167.73 | 163.76 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | -0.03544 | 0.01503 | 713 | -2.36 | 0.0186 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|----------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.06495 | -0.00593 | 0.9652 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9371 | 0.9941 |

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=T_CHOL_U

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.03161 | 0.01495 | 713 | -2.11 | 0.0348 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|----------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.06095 | -0.00226 | 0.9689 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.9409 | 0.9977 |

31: Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C80200S

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 717 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 717 |
| Number of Observations Not Used | 3 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.3464 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1291.7 |
| AIC (Smaller is Better) | 1293.7 |
| AICC (Smaller is Better) | 1293.7 |
| BIC (Smaller is Better) | 1298.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | -0.7292 | 0.06369 | 712 | -11.45 | <.0001 | 0.05 |
| trtpn | | 1 | -0.3934 | 0.05383 | 712 | -7.31 | <.0001 | 0.05 |
| trtpn | | 2 | -0.4788 | 0.06237 | 712 | -7.68 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.03614 | 0.04688 | 712 | -0.77 | 0.4410 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.2984 | 0.05385 | 712 | 5.54 | <.0001 | 0.05 |

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C80200S

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower Upper | |
|----------|--|---|-------------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.4991 | -0.2877 |
| trtpn | | 2 | -0.6013 | -0.3564 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.1282 | 0.05590 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.1927 | 0.4042 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 712 | 35.68 | <.0001 |
| PREOAD2 | 1 | 712 | 0.59 | 0.4410 |
| base_log | 1 | 712 | 30.71 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | -1.3691 | 0.03102 | 712 | -44.14 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | -1.4546 | 0.04415 | 712 | -32.95 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | -0.9757 | 0.04400 | 712 | -22.17 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | -1.4300 | -1.3082 | 0.2543 | 0.2393 | 0.2703 |
| trtpn | LSMeans, IDeg | -1.5413 | -1.3679 | 0.2335 | 0.2141 | 0.2546 |
| trtpn | LSMeans, Lira | -1.0621 | -0.8894 | 0.3769 | 0.3457 | 0.4109 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.08544 | 0.05397 | 712 | 1.58 | 0.1138 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.02052 | 0.1914 | 1.0892 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9797 | 1.2109 |

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C80200S

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.3934 | 0.05383 | 712 | -7.31 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.4991 | -0.2877 | 0.6748 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.6071 | 0.7500 |

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=FFAU

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | aval_log |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 717 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 717 |
| Number of Observations Not Used | 3 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 0.3464 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 1291.7 |
| AIC (Smaller is Better) | 1293.7 |
| AICC (Smaller is Better) | 1293.7 |
| BIC (Smaller is Better) | 1298.3 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 1.6135 | 0.1442 | 712 | 11.19 | <.0001 | 0.05 |
| trtpn | | 1 | -0.3934 | 0.05383 | 712 | -7.31 | <.0001 | 0.05 |
| trtpn | | 2 | -0.4788 | 0.06237 | 712 | -7.68 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.03614 | 0.04688 | 712 | -0.77 | 0.4410 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| base_log | | | 0.2984 | 0.05385 | 712 | 5.54 | <.0001 | 0.05 |

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=FFAU

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|----------|--|---|-----------|---------|
| | | | Intercept | |
| trtpn | | 1 | -0.4991 | -0.2877 |
| trtpn | | 2 | -0.6013 | -0.3564 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.1282 | 0.05590 |
| PREOAD2 | Metformin + OAD | | | |
| base_log | | | 0.1927 | 0.4042 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|----------|-----------|-----------|---------|--------|
| trtpn | 2 | 712 | 35.68 | <.0001 |
| PREOAD2 | 1 | 712 | 0.59 | 0.4410 |
| base_log | 1 | 712 | 30.71 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|-------------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 1.9702 | 0.03102 | 712 | 63.51 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 1.8847 | 0.04415 | 712 | 42.69 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 2.3636 | 0.04400 | 712 | 53.71 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|------------------------|------------------------|
| trtpn | LSMeans, IDegLira | 1.9093 | 2.0311 | 7.1720 | 6.7482 | 7.6223 |
| trtpn | LSMeans, IDeg | 1.7981 | 1.9714 | 6.5847 | 6.0380 | 7.1809 |
| trtpn | LSMeans, Lira | 2.2772 | 2.4500 | 10.6289 | 9.7492 | 11.5880 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|-------------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - IDeg | WORK.ADATA2 | 0.08544 | 0.05397 | 712 | 1.58 | 0.1138 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|----------|--------|---------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.05 | -0.02052 | 0.1914 | 1.0892 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|------------------------|------------------------|
| trtpn | Treatment ratio, IDegLira - IDeg | 0.9797 | 1.2109 |

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=FFAU

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|----------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Treatment ratio, IDegLira - Lira | WORK.ADATA2 | -0.3934 | 0.05383 | 712 | -7.31 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper | Exponentiated |
|--------|----------------------------------|-------|---------|---------|---------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.05 | -0.4991 | -0.2877 | 0.6748 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|----------------------------------|---------------------|---------------------|
| trtpn | Treatment ratio, IDegLira - Lira | 0.6071 | 0.7500 |

32: Hypoglycaemic episodes - treatment emergent - confirmatory statistical analysis - full analysis set

Parameter Code=HYCNFSE

The GENMOD Procedure

Model Information

| | | |
|--------------------|-------------------|----------------|
| Data Set | WORK.ANA_DATA | |
| Distribution | Negative Binomial | |
| Link Function | Log | |
| Dependent Variable | AVAL | Analysis Value |
| Offset Variable | logoff | |

| | |
|-----------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 713 |
| Missing Values | 7 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Parameter Information

| Parameter | Effect | TRTPN | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | TRTPN | 1 | |
| Prm3 | TRTPN | 2 | |
| Prm4 | TRTPN | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |

Iteration History For Parameter Estimates

| Iter | Ridge | Log | | | | | Dispersion |
|------|-------|------------|-----------|-----------|-----------|-----------|------------|
| | | Likelihood | Prm1 | Prm2 | Prm3 | Prm5 | |
| 0 | 0 | -380.13843 | 4.8306049 | -0.036595 | -0.104861 | -0.051602 | 0.8802336 |
| 1 | 16 | -302.60682 | 4.5389129 | -0.1549 | -0.175903 | -0.142035 | 0.9183973 |
| 2 | 16 | -255.22114 | 4.2626473 | -0.251412 | -0.242057 | -0.226961 | 0.9503451 |
| 3 | 1 | -206.65271 | 2.8432976 | 0.1567368 | -0.10993 | -0.427447 | 0.0358785 |
| 4 | 1 | -202.3443 | 2.5892984 | 0.6980844 | 0.2589648 | -0.555308 | 0.0395708 |
| 5 | 1 | -200.99292 | 2.3670321 | 0.9318901 | 0.5113944 | -0.588845 | 0.043325 |
| 6 | 1 | -200.22341 | 2.198899 | 1.1100727 | 0.7072959 | -0.596857 | 0.0478977 |
| 7 | 1 | -199.73835 | 2.0671899 | 1.247524 | 0.8581409 | -0.59647 | 0.0535168 |
| 8 | 1 | -199.39683 | 1.9622075 | 1.3560667 | 0.9762753 | -0.593838 | 0.0605805 |
| 9 | 1 | -199.12347 | 1.8774354 | 1.443274 | 1.070397 | -0.590982 | 0.0697204 |
| 10 | 1 | -198.86994 | 1.8082494 | 1.5142491 | 1.1464569 | -0.588478 | 0.0819888 |
| 11 | 1 | -198.59526 | 1.751282 | 1.5725976 | 1.2086072 | -0.586426 | 0.0992653 |
| 12 | 1 | -198.24946 | 1.7040306 | 1.6209577 | 1.2598201 | -0.584788 | 0.1252315 |
| 13 | 1 | -197.74733 | 1.6646022 | 1.6613144 | 1.302261 | -0.583503 | 0.1680471 |
| 14 | 1 | -196.90293 | 1.6315452 | 1.695204 | 1.3374889 | -0.582535 | 0.2491751 |
| 15 | 1 | -195.23725 | 1.603746 | 1.7238705 | 1.3664613 | -0.581914 | 0.4401437 |
| 16 | 1 | -191.68986 | 1.5804119 | 1.7484509 | 1.389049 | -0.581882 | 1.0431561 |
| 17 | 1 | -187.56845 | 1.5611562 | 1.7700432 | 1.4034058 | -0.582981 | 2.7017295 |
| 18 | 0 | -186.76627 | 1.4976435 | 1.8401498 | 1.4556977 | -0.585191 | 6.8888986 |
| 19 | 0 | -186.39066 | 1.4866145 | 1.8515736 | 1.4690204 | -0.584467 | 5.1881713 |
| 20 | 0 | -186.38768 | 1.4871635 | 1.8506212 | 1.4690617 | -0.584092 | 5.0432744 |
| 21 | 0 | -186.38768 | 1.4871611 | 1.8506254 | 1.4690662 | -0.584093 | 5.0416978 |
| 22 | 0 | -186.38768 | 1.4871611 | 1.8506254 | 1.4690662 | -0.584093 | 5.0416978 |

Hypoglycaemic episodes - treatment emergent - confirmatory statistical analysis - full analysis set

Parameter Code=HYCNFSE

The GENMOD Procedure

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|-----|-----------|----------|
| Deviance | 709 | 178.6787 | 0.2520 |
| Scaled Deviance | 709 | 178.6787 | 0.2520 |
| Pearson Chi-Square | 709 | 910.8445 | 1.2847 |
| Scaled Pearson X2 | 709 | 910.8445 | 1.2847 |
| Log Likelihood | | -186.3877 | |
| Full Log Likelihood | | -197.5958 | |
| AIC (smaller is better) | | 405.1916 | |
| AICC (smaller is better) | | 405.2765 | |
| BIC (smaller is better) | | 428.0391 | |

Last Evaluation Of The Negative Of The Gradient and Hessian

| | Prm1 | Prm2 | Prm3 | Prm5 | Dispersion |
|------------|-----------|-----------|-----------|-----------|------------|
| Gradient | 4.5021E-9 | 8.37E-9 | 7.528E-10 | -1.755E-9 | 5.4659E-8 |
| Prm1 | 39.194138 | 26.152514 | 10.311714 | 9.5802638 | 0.0027883 |
| Prm2 | 26.152514 | 26.152514 | 0 | 6.9340316 | -0.018622 |
| Prm3 | 10.311714 | 0 | 10.311714 | 2.00561 | 0.0446241 |
| Prm5 | 9.5802638 | 6.9340316 | 2.00561 | 9.5802638 | 0.0038538 |
| Dispersion | 0.0027883 | -0.018622 | 0.0446241 | 0.0038538 | 0.2835077 |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|----------------------------|-----------------|------------|
| Intercept | 1 | 1.4872 | 0.6117 | 0.2882 2.6861 | 5.91 | 0.0151 |
| TRTPN 1 | 1 | 1.8506 | 0.6363 | 0.6035 3.0978 | 8.46 | 0.0036 |
| TRTPN 2 | 1 | 1.4691 | 0.6812 | 0.1338 2.8043 | 4.65 | 0.0310 |
| TRTPN 3 | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| PREOAD2 Metformin | 1 | -0.5841 | 0.3726 | -1.3145 0.1463 | 2.46 | 0.1170 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| Dispersion | 1 | 5.0417 | 1.8794 | 2.4281 10.4686 | | |

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

TRTPN Least Squares Means

| Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper | Exponentiated |
|-----------------------|----------|----------------|---------|---------|-------|----------|--------|---------------|
| 1 | 3.0457 | 0.2142 | 14.22 | <.0001 | 0.05 | 2.6258 | 3.4656 | 21.0256 |
| 2 | 2.6642 | 0.3317 | 8.03 | <.0001 | 0.05 | 2.0141 | 3.3143 | 14.3562 |
| 3 | 1.1951 | 0.6135 | 1.95 | 0.0514 | 0.05 | -0.00724 | 2.3975 | 3.3039 |

TRTPN Least Squares Means

| Planned Treatment (N) | Exponentiated Lower | Exponentiated Upper |
|-----------------------|---------------------|---------------------|
| 1 | 13.8162 | 31.9969 |
| 2 | 7.4940 | 27.5020 |
| 3 | 0.9928 | 10.9953 |

Hypoglycaemic episodes - treatment emergent - confirmatory statistical analysis - full analysis set

Parameter Code=HYCNFSE

The GENMOD Procedure

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|-----------------------|-----------------------|----------|----------------|---------|---------|-------|---------|--------|
| 1 | 2 | 0.3816 | 0.3688 | 1.03 | 0.3008 | 0.05 | -0.3412 | 1.1044 |
| 1 | 3 | 1.8506 | 0.6363 | 2.91 | 0.0036 | 0.05 | 0.6035 | 3.0978 |
| 2 | 3 | 1.4691 | 0.6812 | 2.16 | 0.0310 | 0.05 | 0.1338 | 2.8043 |

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|-----------------------|-----------------------|---------------|---------------------|---------------------|
| 1 | 2 | 1.4646 | 0.7109 | 3.0173 |
| 1 | 3 | 6.3638 | 1.8285 | 22.1486 |
| 2 | 3 | 4.3452 | 1.1432 | 16.5153 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|--------|-----------------|----------|----------------|---------|---------|-------|---------|--------|
| TRTPN | IDegLira / IDeg | 0.3816 | 0.3688 | 1.03 | 0.3008 | 0.05 | -0.3412 | 1.1044 |
| TRTPN | IDegLira / Lira | 1.8506 | 0.6363 | 2.91 | 0.0036 | 0.05 | 0.6035 | 3.0978 |

Least Squares Means Estimates

| Effect | Label | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------|---------------|---------------------|---------------------|
| TRTPN | IDegLira / IDeg | 1.4646 | 0.7109 | 3.0173 |
| TRTPN | IDegLira / Lira | 6.3638 | 1.8285 | 22.1486 |

33: Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=2 Parameter Code=HYCNFSE Planned Treatment (N)=1 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000963 | 0.044886 | 0.045849 | 2.26E6 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.021473 | 0.021022 | 0.999979 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 3.038074 | 0.214125 | 2.618397 | 3.457751 | 2.26E6 | 2.986481 | 3.203014 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 14.19 | <.0001 |

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=2 Parameter Code=HYCNFSE Planned Treatment (N)=2 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.002318 | 0.107840 | 0.110161 | 2.25E6 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.021518 | 0.021065 | 0.999979 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 2.665038 | 0.331905 | 2.014517 | 3.315560 | 2.25E6 | 2.592518 | 2.921904 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 8.03 | <.0001 |

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=2 Parameter Code=HYCNFSE Planned Treatment (N)=3 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI2
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.039026 | 0.334826 | 0.373891 | 91512 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.116673 | 0.104502 | 0.999896 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|-------|----------|----------|
| Estimate | 1.177674 | 0.611466 | -0.02079 | 2.376142 | 91512 | 1.003454 | 2.309467 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 1.93 | 0.0541 |

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=2 Parameter Code=HYCNFSE Label=IDegLira / IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

| | |
|-----------------------|---------------|
| Data Set | WORK.LSME_MI2 |
| Number of Imputations | 1000 |

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-----|
| | Between | Within | Total | |
| Estimate | 0.002478 | 0.133550 | 0.136031 | 3E6 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.018575 | 0.018237 | 0.999982 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|-----|----------|----------|
| Estimate | 0.373036 | 0.368824 | -0.34985 | 1.095918 | 3E6 | 0.121602 | 0.511817 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: | |
|-----------|--------|------------------|---------|
| | | Parameter=Theta0 | Pr > t |
| Estimate | 0 | 1.01 | 0.3118 |

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=3 Parameter Code=HYCNFSE Planned Treatment (N)=1 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.000309 | 0.045685 | 0.045994 | 2.22E7 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.006760 | 0.006715 | 0.999993 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 3.020836 | 0.214463 | 2.600497 | 3.441176 | 2.22E7 | 2.985600 | 3.127575 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 14.09 | <.0001 |

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=3 Parameter Code=HYCNFSE Planned Treatment (N)=2 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.002102 | 0.108684 | 0.110788 | 2.77E6 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.019355 | 0.018989 | 0.999981 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 2.662611 | 0.332848 | 2.010241 | 3.314982 | 2.77E6 | 2.602009 | 2.921904 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|-------------------------------|---------|
| Estimate | 0 | 8.00 | <.0001 |

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=3 Parameter Code=HYCNFSE Planned Treatment (N)=3 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|-------|
| | Between | Within | Total | |
| Estimate | 0.038929 | 0.335631 | 0.374599 | 92316 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.116104 | 0.104046 | 0.999896 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|-------|----------|----------|
| Estimate | 1.175999 | 0.612045 | -0.02360 | 2.375601 | 92316 | 1.005759 | 2.300105 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 1.92 | 0.0547 |

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

ANA_SORT=3 Parameter Code=HYCNFSE Label=IDegLira / Lira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_MI3
 Number of Imputations 1000

Variance Information (1000 Imputations)

| Parameter | -----Variance----- | | | DF |
|-----------|--------------------|----------|----------|--------|
| | Between | Within | Total | |
| Estimate | 0.038461 | 0.363910 | 0.402410 | 109140 |

Variance Information (1000 Imputations)

| Parameter | Relative Increase in Variance | Fraction Missing Information | Relative Efficiency |
|-----------|-------------------------------|------------------------------|---------------------|
| Estimate | 0.105795 | 0.095690 | 0.999904 |

Parameter Estimates (1000 Imputations)

| Parameter | Estimate | Std Error | 95% Confidence Limits | | DF | Minimum | Maximum |
|-----------|----------|-----------|-----------------------|----------|--------|----------|----------|
| Estimate | 1.844837 | 0.634358 | 0.601505 | 3.088170 | 109140 | 0.750524 | 2.067895 |

Parameter Estimates (1000 Imputations)

| Parameter | Theta0 | t for H0: Parameter=Theta0 | Pr > t |
|-----------|--------|----------------------------|---------|
| Estimate | 0 | 2.91 | 0.0036 |

34: Hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYCNFSES

The GENMOD Procedure

Model Information

| | | |
|--------------------|-------------------|----------------|
| Data Set | WORK.ANA_DATA | |
| Distribution | Negative Binomial | |
| Link Function | Log | |
| Dependent Variable | AVAL | Analysis Value |
| Offset Variable | logoff | |

| | |
|-----------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 713 |
| Missing Values | 7 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Parameter Information

| Parameter | Effect | TRTPN | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | TRTPN | 1 | |
| Prm3 | TRTPN | 2 | |
| Prm4 | TRTPN | 3 | |
| Prm5 | PREOAD2 | | Metformin |
| Prm6 | PREOAD2 | | Metformin + OAD |

Iteration History For Parameter Estimates

| Iter | Ridge | Log Likelihood | Prm1 | Prm2 | Prm3 | Prm5 | Dispersion |
|------|-------|----------------|-----------|-----------|-----------|-----------|------------|
| 0 | 0 | -353.06722 | 4.8066601 | -0.074818 | -0.131729 | -0.020934 | 0.861409 |
| 1 | 16 | -266.30919 | 4.49535 | -0.204286 | -0.209027 | -0.112915 | 0.8962711 |
| 2 | 16 | -210.74259 | 4.1900096 | -0.317233 | -0.284518 | -0.199872 | 0.9218333 |
| 3 | 16 | -173.55805 | 3.8503107 | -0.415706 | -0.366987 | -0.291605 | 0.9418687 |
| 4 | 1 | -143.6538 | 3.0355129 | -0.140169 | -0.327641 | -0.370119 | 0.8064204 |
| 5 | 1 | -135.39985 | 2.4869883 | 0.2781764 | -0.163044 | -0.420301 | 1.5551127 |
| 6 | 1 | -131.14278 | 2.0944005 | 0.6753206 | 0.0960382 | -0.432245 | 3.435585 |
| 7 | 0 | -128.32846 | 1.2717192 | 1.5420922 | 1.0071474 | -0.38109 | 8.3037715 |
| 8 | 0 | -127.62792 | 0.5784988 | 2.2398711 | 1.7079566 | -0.362035 | 6.2854472 |
| 9 | 0 | -127.59326 | 0.3486607 | 2.469668 | 1.937593 | -0.365232 | 6.226675 |
| 10 | 0 | -127.59288 | 0.3209942 | 2.4973578 | 1.9652698 | -0.365305 | 6.2291019 |
| 11 | 0 | -127.59288 | 0.3206337 | 2.4977184 | 1.9656304 | -0.365306 | 6.2291245 |
| 12 | 0 | -127.59288 | 0.3206337 | 2.4977184 | 1.9656304 | -0.365306 | 6.2291245 |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|-----|-----------|----------|
| Deviance | 709 | 123.9740 | 0.1749 |
| Scaled Deviance | 709 | 123.9740 | 0.1749 |
| Pearson Chi-Square | 709 | 1089.6976 | 1.5370 |
| Scaled Pearson X2 | 709 | 1089.6976 | 1.5370 |
| Log Likelihood | | -127.5929 | |
| Full Log Likelihood | | -132.8504 | |
| AIC (smaller is better) | | 275.7008 | |
| AICC (smaller is better) | | 275.7856 | |
| BIC (smaller is better) | | 298.5482 | |

Hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYCNFSES

The GENMOD Procedure

Last Evaluation Of The Negative Of The Gradient and Hessian

| | Prm1 | Prm2 | Prm3 | Prm5 | Dispersion |
|------------|-----------|-----------|-----------|-----------|------------|
| Gradient | 5.7947E-8 | -5.49E-13 | 7.89E-13 | 1.6345E-8 | -6.43E-10 |
| Prm1 | 25.276692 | 18.132024 | 6.1824107 | 6.7687429 | 0.0081878 |
| Prm2 | 18.132024 | 18.132024 | 0 | 5.2170454 | -0.004494 |
| Prm3 | 6.1824107 | 0 | 6.1824107 | 1.2857398 | 0.0171082 |
| Prm5 | 6.7687429 | 5.2170454 | 1.2857398 | 6.7687429 | -0.006032 |
| Dispersion | 0.0081878 | -0.004494 | 0.0171082 | -0.006032 | 0.1016866 |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|----------------------------|-----------------|------------|
| Intercept | 1 | 0.3206 | 1.0271 | -1.6924 2.3337 | 0.10 | 0.7549 |
| TRTPN 1 | 1 | 2.4977 | 1.0462 | 0.4472 4.5483 | 5.70 | 0.0170 |
| TRTPN 2 | 1 | 1.9656 | 1.0966 | -0.1836 4.1148 | 3.21 | 0.0730 |
| TRTPN 3 | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| PREOAD2 Metformin | 1 | -0.3653 | 0.4505 | -1.2484 0.5178 | 0.66 | 0.4175 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| Dispersion | 1 | 6.2291 | 3.1372 | 2.3213 16.7154 | | |

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

TRTPN Least Squares Means

| Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper | Exponentiated |
|-----------------------|----------|----------------|---------|---------|-------|---------|--------|---------------|
| 1 | 2.6357 | 0.2536 | 10.39 | <.0001 | 0.05 | 2.1387 | 3.1327 | 13.9531 |
| 2 | 2.1036 | 0.4232 | 4.97 | <.0001 | 0.05 | 1.2741 | 2.9331 | 8.1957 |
| 3 | 0.1380 | 1.0245 | 0.13 | 0.8929 | 0.05 | -1.8700 | 2.1460 | 1.1480 |

TRTPN Least Squares Means

| Planned Treatment (N) | Exponentiated Lower | Exponentiated Upper |
|-----------------------|---------------------|---------------------|
| 1 | 8.4884 | 22.9357 |
| 2 | 3.5755 | 18.7858 |
| 3 | 0.1541 | 8.5504 |

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|-----------------------|-----------------------|----------|----------------|---------|---------|-------|---------|--------|
| 1 | 2 | 0.5321 | 0.4672 | 1.14 | 0.2547 | 0.05 | -0.3836 | 1.4478 |

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|-----------------------|-----------------------|---------------|---------------------|---------------------|
| 1 | 2 | 1.7025 | 0.6814 | 4.2537 |

Hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYCNFSES

The GENMOD Procedure

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|-----------------------|-----------------------|----------|----------------|---------|---------|-------|---------|--------|
| 1 | 3 | 2.4977 | 1.0462 | 2.39 | 0.0170 | 0.05 | 0.4472 | 4.5483 |
| 2 | 3 | 1.9656 | 1.0966 | 1.79 | 0.0730 | 0.05 | -0.1836 | 4.1148 |

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|-----------------------|-----------------------|---------------|---------------------|---------------------|
| 1 | 3 | 12.1547 | 1.5639 | 94.4701 |
| 2 | 3 | 7.1394 | 0.8323 | 61.2429 |

Least Squares Means Estimates

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|--------|-----------------|----------|----------------|---------|---------|-------|---------|--------|
| TRTPN | IDegLira / IDeg | 0.5321 | 0.4672 | 1.14 | 0.2547 | 0.05 | -0.3836 | 1.4478 |
| TRTPN | IDegLira / Lira | 2.4977 | 1.0462 | 2.39 | 0.0170 | 0.05 | 0.4472 | 4.5483 |

Least Squares Means Estimates

| Effect | Label | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------|---------------|---------------------|---------------------|
| TRTPN | IDegLira / IDeg | 1.7025 | 0.6814 | 4.2537 |
| TRTPN | IDegLira / Lira | 12.1547 | 1.5639 | 94.4701 |

35: Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSSE

The GENMOD Procedure

Model Information

| | | |
|--------------------|-------------------|----------------|
| Data Set | WORK.ANA_DATA | |
| Distribution | Negative Binomial | |
| Link Function | Log | |
| Dependent Variable | AVAL | Analysis Value |
| Offset Variable | logoff | |

| | |
|-----------------------------|-----|
| Number of Observations Read | 540 |
| Number of Observations Used | 533 |
| Missing Values | 7 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 2 | 1 2 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Parameter Information

| Parameter | Effect | TRTPN | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | TRTPN | 1 | |
| Prm3 | TRTPN | 2 | |
| Prm4 | PREOAD2 | | Metformin |
| Prm5 | PREOAD2 | | Metformin + OAD |

Iteration History For Parameter Estimates

| Iter | Ridge | Log Likelihood | Prm1 | Prm2 | Prm4 | Dispersion |
|------|-------|----------------|-----------|-----------|-----------|------------|
| 0 | 0 | -243.64107 | 4.637979 | 0.0194619 | 0.0260575 | 0.8386892 |
| 1 | 16 | -184.26619 | 4.3981381 | -0.1288 | -0.045806 | 0.8662332 |
| 2 | 1 | -68.411958 | 2.935821 | -0.434955 | -0.206637 | 0.0121826 |
| 3 | 0.06 | -58.692105 | 2.1873247 | -0.320872 | -0.130925 | 0.0128597 |
| 4 | 0.06 | -57.230315 | 1.7003907 | -0.150367 | -0.025395 | 0.0151914 |
| 5 | 0.06 | -57.13682 | 1.5241268 | -0.041456 | 0.0331984 | 0.0206355 |
| 6 | 0.06 | -57.110943 | 1.4998604 | -0.020569 | 0.0424738 | 0.0343106 |
| 7 | 0.06 | -56.971669 | 1.4982316 | -0.018939 | 0.0431973 | 0.1151813 |
| 8 | 1 | -56.947602 | 1.4981784 | -0.018898 | 0.0432318 | 0.1298369 |
| 9 | 1 | -56.917385 | 1.4981527 | -0.018879 | 0.0432527 | 0.1485335 |
| 10 | 1 | -56.878466 | 1.4981399 | -0.018875 | 0.0432673 | 0.1731113 |
| 11 | 1 | -56.826753 | 1.4981338 | -0.018879 | 0.0432803 | 0.2066582 |
| 12 | 1 | -56.755364 | 1.4981313 | -0.018892 | 0.043295 | 0.2547 |
| 13 | 1 | -56.652094 | 1.498131 | -0.018915 | 0.0433146 | 0.32794 |
| 14 | 1 | -56.494193 | 1.4981321 | -0.018952 | 0.0433443 | 0.4491921 |
| 15 | 1 | -56.238368 | 1.4981344 | -0.019017 | 0.043395 | 0.6726469 |
| 16 | 1 | -55.810424 | 1.4981378 | -0.019144 | 0.0434916 | 1.1394896 |
| 17 | 1 | -55.147082 | 1.4981417 | -0.019409 | 0.0436941 | 2.2055893 |
| 18 | 1 | -54.385791 | 1.498142 | -0.019956 | 0.0441147 | 4.4431574 |
| 19 | 0 | -54.054726 | 1.498489 | -0.023739 | 0.0471084 | 38.111462 |
| 20 | 0 | -53.520173 | 1.4987877 | -0.02712 | 0.0502384 | 19.488384 |
| 21 | 0 | -53.506363 | 1.4984434 | -0.02461 | 0.0479554 | 17.083396 |
| 22 | 0 | -53.506335 | 1.4984612 | -0.024704 | 0.0480491 | 16.976997 |
| 23 | 0 | -53.506335 | 1.4984612 | -0.024704 | 0.0480488 | 16.976758 |

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSE

The GENMOD Procedure

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|-----|----------|----------|
| Deviance | 530 | 45.8965 | 0.0866 |
| Scaled Deviance | 530 | 45.8965 | 0.0866 |
| Pearson Chi-Square | 530 | 488.5132 | 0.9217 |
| Scaled Pearson X2 | 530 | 488.5132 | 0.9217 |
| Log Likelihood | | -53.5063 | |
| Full Log Likelihood | | -54.8926 | |
| AIC (smaller is better) | | 117.7853 | |
| AICC (smaller is better) | | 117.8610 | |
| BIC (smaller is better) | | 134.8993 | |

Last Evaluation Of The Negative Of The Gradient and Hessian

| | Prm1 | Prm2 | Prm4 | Dispersion |
|------------|-----------|-----------|-----------|------------|
| Gradient | 1.703E-12 | 3.889E-12 | -2.15E-12 | 5.95E-12 |
| Prm1 | 8.6322112 | 5.7634921 | 2.8522502 | 0.0009603 |
| Prm2 | 5.7634921 | 5.7634921 | 2.1928143 | 0.0011125 |
| Prm4 | 2.8522502 | 2.1928143 | 2.8522502 | -0.000068 |
| Dispersion | 0.0009603 | 0.0011125 | -0.000068 | 0.0048804 |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|----------------------------|-----------------|------------|
| Intercept | 1 | 1.4985 | 0.6139 | 0.2952 2.7017 | 5.96 | 0.0147 |
| TRTPN 1 | 1 | -0.0247 | 0.7309 | -1.4573 1.4079 | 0.00 | 0.9730 |
| TRTPN 2 | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| PREOAD2 Metformin | 1 | 0.0480 | 0.7320 | -1.3866 1.4827 | 0.00 | 0.9477 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| Dispersion | 1 | 16.9768 | 14.3149 | 3.2518 88.6320 | | |

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

TRTPN Least Squares Means

| Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper | Exponentiated |
|-----------------------|----------|----------------|---------|---------|-------|--------|--------|---------------|
| 1 | 1.4978 | 0.4256 | 3.52 | 0.0004 | 0.05 | 0.6635 | 2.3320 | 4.4718 |
| 2 | 1.5225 | 0.6226 | 2.45 | 0.0145 | 0.05 | 0.3021 | 2.7428 | 4.5836 |

TRTPN Least Squares Means

| Planned Treatment (N) | Exponentiated Lower | Exponentiated Upper |
|-----------------------|---------------------|---------------------|
| 1 | 1.9417 | 10.2987 |
| 2 | 1.3527 | 15.5312 |

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSE

The GENMOD Procedure

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|-----------------------|-----------------------|----------|----------------|---------|---------|-------|---------|--------|
| 1 | 2 | -0.02470 | 0.7309 | -0.03 | 0.9730 | 0.05 | -1.4573 | 1.4079 |

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|-----------------------|-----------------------|---------------|---------------------|---------------------|
| 1 | 2 | 0.9756 | 0.2329 | 4.0873 |

Least Squares Means Estimate

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|--------|-----------------|----------|----------------|---------|---------|-------|---------|--------|
| TRTPN | IDegLira / IDeg | -0.02470 | 0.7309 | -0.03 | 0.9730 | 0.05 | -1.4573 | 1.4079 |

Least Squares Means Estimate

| Effect | Label | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------|---------------|---------------------|---------------------|
| TRTPN | IDegLira / IDeg | 0.9756 | 0.2329 | 4.0873 |

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSES

The GENMOD Procedure

Model Information

| | | |
|--------------------|-------------------|----------------|
| Data Set | WORK.ANA_DATA | |
| Distribution | Negative Binomial | |
| Link Function | Log | |
| Dependent Variable | AVAL | Analysis Value |
| Offset Variable | logoff | |

| | |
|-----------------------------|-----|
| Number of Observations Read | 540 |
| Number of Observations Used | 533 |
| Missing Values | 7 |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| TRTPN | 2 | 1 2 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Parameter Information

| Parameter | Effect | TRTPN | PREOAD2 |
|-----------|-----------|-------|-----------------|
| Prm1 | Intercept | | |
| Prm2 | TRTPN | 1 | |
| Prm3 | TRTPN | 2 | |
| Prm4 | PREOAD2 | | Metformin |
| Prm5 | PREOAD2 | | Metformin + OAD |

Iteration History For Parameter Estimates

| Iter | Ridge | Log Likelihood | Prm1 | Prm2 | Prm4 | Dispersion |
|------|-------|----------------|-----------|-----------|-----------|------------|
| 0 | 0 | -239.38395 | 4.6320803 | 0.0130252 | 0.0267412 | 0.8307234 |
| 1 | 16 | -178.5201 | 4.3885276 | -0.137679 | -0.045836 | 0.8568435 |
| 2 | 1 | -52.915 | 2.7724072 | -0.477285 | -0.213908 | 0.0055764 |
| 3 | 0.06 | -43.169463 | 1.9833211 | -0.422206 | -0.099201 | 0.0055064 |
| 4 | 0 | -41.402752 | 1.4086308 | -0.303289 | 0.0916114 | 0.0000105 |
| 5 | 0 | -41.279967 | 1.1755251 | -0.21786 | 0.2104166 | 3.6292E-6 |
| 6 | 0 | -41.278755 | 1.1467312 | -0.202954 | 0.2269668 | 1.4011E-6 |
| 7 | 0 | -41.278755 | 1.1463672 | -0.202723 | 0.227155 | 4.7003E-7 |
| 8 | 0 | -41.278755 | 1.1463672 | -0.202723 | 0.227155 | 4.7001E-7 |

Criteria For Assessing Goodness Of Fit

| Criterion | DF | Value | Value/DF |
|--------------------------|-----|----------|----------|
| Deviance | 530 | 66.5575 | 0.1256 |
| Scaled Deviance | 530 | 66.5575 | 0.1256 |
| Pearson Chi-Square | 530 | 506.8188 | 0.9563 |
| Scaled Pearson X2 | 530 | 506.8188 | 0.9563 |
| Log Likelihood | | -41.2788 | |
| Full Log Likelihood | | -41.2788 | |
| AIC (smaller is better) | | 90.5575 | |
| AICC (smaller is better) | | 90.6333 | |
| BIC (smaller is better) | | 107.6716 | |

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSES

The GENMOD Procedure

Last Evaluation Of The Negative Of The Gradient and Hessian

| | Prm1 | Prm2 | Prm4 | Dispersion |
|------------|-----------|-----------|-----------|------------|
| Gradient | 1.7262E-7 | 3.2856E-8 | 1.7575E-8 | 0.0300508 |
| Prm1 | 8.0000001 | 5 | 3 | -0.000228 |
| Prm2 | 5 | 5 | 1.8918351 | 0.0041442 |
| Prm4 | 3 | 1.8918351 | 3 | -0.004008 |
| Dispersion | -0.000228 | 0.0041442 | -0.004008 | 141409.99 |

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

| Parameter | DF | Estimate | Standard Error | Wald 95% Confidence Limits | Wald Chi-Square | Pr > ChiSq |
|-------------------------|----|----------|----------------|----------------------------|-----------------|------------|
| Intercept | 1 | 1.1464 | 0.6373 | -0.1027 2.3954 | 3.24 | 0.0720 |
| TRTPN 1 | 1 | -0.2027 | 0.7303 | -1.6341 1.2287 | 0.08 | 0.7813 |
| TRTPN 2 | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| PREOAD2 Metformin | 1 | 0.2272 | 0.7303 | -1.2043 1.6586 | 0.10 | 0.7558 |
| PREOAD2 Metformin + OAD | 0 | 0.0000 | 0.0000 | 0.0000 0.0000 | | |
| Dispersion | 1 | 0.0000 | 0.0027 | | | |

NOTE: The negative binomial dispersion parameter was estimated by maximum likelihood.

TRTPN Least Squares Means

| Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper | Exponentiated |
|-----------------------|----------|----------------|---------|---------|-------|--------|--------|---------------|
| 1 | 1.0572 | 0.4560 | 2.32 | 0.0204 | 0.05 | 0.1636 | 1.9509 | 2.8784 |
| 2 | 1.2599 | 0.5852 | 2.15 | 0.0313 | 0.05 | 0.1130 | 2.4069 | 3.5252 |

TRTPN Least Squares Means

| Planned Treatment (N) | Exponentiated Lower | Exponentiated Upper |
|-----------------------|---------------------|---------------------|
| 1 | 1.1777 | 7.0348 |
| 2 | 1.1197 | 11.0992 |

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|-----------------------|-----------------------|----------|----------------|---------|---------|-------|---------|--------|
| 1 | 2 | -0.2027 | 0.7303 | -0.28 | 0.7813 | 0.05 | -1.6341 | 1.2287 |

Differences of TRTPN Least Squares Means

| Planned Treatment (N) | Planned Treatment (N) | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|-----------------------|-----------------------|---------------|---------------------|---------------------|
| 1 | 2 | 0.8165 | 0.1951 | 3.4168 |

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSES

The GENMOD Procedure

Least Squares Means Estimate

| Effect | Label | Estimate | Standard Error | z Value | Pr > z | Alpha | Lower | Upper |
|--------|-----------------|----------|----------------|---------|---------|-------|---------|--------|
| TRTPN | IDegLira / IDeg | -0.2027 | 0.7303 | -0.28 | 0.7813 | 0.05 | -1.6341 | 1.2287 |

Least Squares Means Estimate

| Effect | Label | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-----------------|---------------|---------------------|---------------------|
| TRTPN | IDegLira / IDeg | 0.8165 | 0.1951 | 3.4168 |

36: Pulse after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C49676X

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 61.0988 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5001.9 |
| AIC (Smaller is Better) | 5003.9 |
| AICC (Smaller is Better) | 5003.9 |
| BIC (Smaller is Better) | 5008.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 39.7507 | 2.4558 | 715 | 16.19 | <.0001 | 0.05 |
| trtpn | | 1 | -1.1609 | 0.7136 | 715 | -1.63 | 0.1042 | 0.05 |
| trtpn | | 2 | -5.4522 | 0.8252 | 715 | -6.61 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.1803 | 0.6226 | 715 | -0.29 | 0.7722 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.5538 | 0.03075 | 715 | 18.01 | <.0001 | 0.05 |

Pulse after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C49676X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 34.9293 | 44.5720 |
| trtpn | | 1 | -2.5619 | 0.2401 |
| trtpn | | 2 | -7.0723 | -3.8322 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -1.4025 | 1.0420 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.4934 | 0.6142 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 25.41 | <.0001 |
| PREOAD2 | 1 | 715 | 0.08 | 0.7722 |
| BASE | 1 | 715 | 324.30 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 81.2475 | 0.4115 | 715 | 197.44 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 76.9561 | 0.5843 | 715 | 131.71 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 82.4084 | 0.5828 | 715 | 141.41 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 80.4396 | 82.0554 | 1.929E35 | 8.6E34 | 4.327E35 |
| trtpn | LSMeans, IDeg | 75.8090 | 78.1032 | 2.64E33 | 8.384E32 | 8.314E33 |
| trtpn | LSMeans, Lira | 81.2642 | 83.5525 | 6.159E35 | 1.962E35 | 1.934E36 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | 4.2914 | 0.7147 | 715 | 6.00 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|--------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | <.0001 | 0.05 | 2.8882 | 5.6945 | 73.0660 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 17.9611 | 297.23 |

Pulse after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C49676X

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -1.1609 | 0.7136 | 715 | -1.63 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.1042 | 0.05 | -2.5619 | 0.2401 | 0.3132 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.07716 | 1.2714 |

Pulse after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C49676X

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 61.0988 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5001.9 |
| AIC (Smaller is Better) | 5003.9 |
| AICC (Smaller is Better) | 5003.9 |
| BIC (Smaller is Better) | 5008.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 39.7507 | 2.4558 | 715 | 16.19 | <.0001 | 0.05 |
| trtpn | | 1 | -1.1609 | 0.7136 | 715 | -1.63 | 0.1042 | 0.05 |
| trtpn | | 2 | -5.4522 | 0.8252 | 715 | -6.61 | <.0001 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.1803 | 0.6226 | 715 | -0.29 | 0.7722 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.4462 | 0.03075 | 715 | -14.51 | <.0001 | 0.05 |

Pulse after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=C49676X

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 34.9293 | 44.5720 |
| trtpn | | 1 | -2.5619 | 0.2401 |
| trtpn | | 2 | -7.0723 | -3.8322 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -1.4025 | 1.0420 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.5066 | -0.3858 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 25.41 | <.0001 |
| PREOAD2 | 1 | 715 | 0.08 | 0.7722 |
| BASE | 1 | 715 | 210.49 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | 4.1169 | 0.4115 | 715 | 10.00 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -0.1744 | 0.5843 | 715 | -0.30 | 0.7654 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | 5.2778 | 0.5828 | 715 | 9.06 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|--------|
| trtpn | Change from baseline, IDegLira | 0.05 | 3.3090 | 4.9248 |
| trtpn | Change from baseline, IDeg | 0.05 | -1.3215 | 0.9727 |
| trtpn | Change from baseline, Lira | 0.05 | 4.1337 | 6.4220 |

37: Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=SYSBPMEA

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 112.91 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5441.9 |
| AIC (Smaller is Better) | 5443.9 |
| AICC (Smaller is Better) | 5443.9 |
| BIC (Smaller is Better) | 5448.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 54.8951 | 3.5822 | 715 | 15.32 | <.0001 | 0.05 |
| trtpn | | 1 | 0.3202 | 0.9699 | 715 | 0.33 | 0.7414 | 0.05 |
| trtpn | | 2 | 2.3622 | 1.1218 | 715 | 2.11 | 0.0356 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.1735 | 0.8456 | 715 | -0.21 | 0.8375 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.5459 | 0.02725 | 715 | 20.03 | <.0001 | 0.05 |

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=SYSBPMEA

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 47.8622 | 61.9280 |
| trtpn | | 1 | -1.5840 | 2.2244 |
| trtpn | | 2 | 0.1598 | 4.5646 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -1.8337 | 1.4867 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.4924 | 0.5994 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 2.80 | 0.0613 |
| PREOAD2 | 1 | 715 | 0.04 | 0.8375 |
| BASE | 1 | 715 | 401.30 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 125.34 | 0.5593 | 715 | 224.09 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 127.38 | 0.7942 | 715 | 160.38 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 125.02 | 0.7922 | 715 | 157.81 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|--------|--------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 124.24 | 126.44 | 2.717E54 | 9.06E53 | 8.147E54 |
| trtpn | LSMeans, IDeg | 125.82 | 128.94 | 2.094E55 | 4.402E54 | 9.956E55 |
| trtpn | LSMeans, Lira | 123.46 | 126.57 | 1.972E54 | 4.164E53 | 9.342E54 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | -2.0420 | 0.9715 | 715 | -2.10 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|---------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.0359 | 0.05 | -3.9492 | -0.1347 | 0.1298 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.01927 | 0.8739 |

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=SYSBPMEA

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | 0.3202 | 0.9699 | 715 | 0.33 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.7414 | 0.05 | -1.5840 | 2.2244 | 1.3774 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.2052 | 9.2480 |

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=SYSBPMEA

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 112.91 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 5441.9 |
| AIC (Smaller is Better) | 5443.9 |
| AICC (Smaller is Better) | 5443.9 |
| BIC (Smaller is Better) | 5448.5 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 54.8951 | 3.5822 | 715 | 15.32 | <.0001 | 0.05 |
| trtpn | | 1 | 0.3202 | 0.9699 | 715 | 0.33 | 0.7414 | 0.05 |
| trtpn | | 2 | 2.3622 | 1.1218 | 715 | 2.11 | 0.0356 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | -0.1735 | 0.8456 | 715 | -0.21 | 0.8375 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.4541 | 0.02725 | 715 | -16.66 | <.0001 | 0.05 |

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=SYSBPMEA

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 47.8622 | 61.9280 |
| trtpn | | 1 | -1.5840 | 2.2244 |
| trtpn | | 2 | 0.1598 | 4.5646 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -1.8337 | 1.4867 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.5076 | -0.4006 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 2.80 | 0.0613 |
| PREOAD2 | 1 | 715 | 0.04 | 0.8375 |
| BASE | 1 | 715 | 277.68 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -3.2197 | 0.5593 | 715 | -5.76 | <.0001 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -1.1778 | 0.7942 | 715 | -1.48 | 0.1386 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -3.5399 | 0.7922 | 715 | -4.47 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|---------|
| trtpn | Change from baseline, IDegLira | 0.05 | -4.3179 | -2.1216 |
| trtpn | Change from baseline, IDeg | 0.05 | -2.7371 | 0.3816 |
| trtpn | Change from baseline, Lira | 0.05 | -5.0953 | -1.9846 |

38: Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=DIABPMEA

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | AVAL |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 50.4183 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4864.5 |
| AIC (Smaller is Better) | 4866.5 |
| AICC (Smaller is Better) | 4866.5 |
| BIC (Smaller is Better) | 4871.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 33.7874 | 2.3740 | 715 | 14.23 | <.0001 | 0.05 |
| trtpn | | 1 | -0.2455 | 0.6479 | 715 | -0.38 | 0.7049 | 0.05 |
| trtpn | | 2 | -0.8356 | 0.7496 | 715 | -1.11 | 0.2653 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6531 | 0.5681 | 715 | 1.15 | 0.2507 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | 0.5735 | 0.02907 | 715 | 19.73 | <.0001 | 0.05 |

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=DIABPMEA

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 29.1266 | 38.4483 |
| trtpn | | 1 | -1.5175 | 1.0265 |
| trtpn | | 2 | -2.3072 | 0.6360 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.4622 | 1.7685 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | 0.5165 | 0.6306 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 0.67 | 0.5102 |
| PREOAD2 | 1 | 715 | 1.32 | 0.2507 |
| BASE | 1 | 715 | 389.16 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|--------|-------------------|-------------|----------|----------------|-----|---------|---------|-------|
| trtpn | LSMeans, IDegLira | WORK.ADATA2 | 79.6002 | 0.3737 | 715 | 212.99 | <.0001 | 0.05 |
| trtpn | LSMeans, IDeg | WORK.ADATA2 | 79.0100 | 0.5308 | 715 | 148.86 | <.0001 | 0.05 |
| trtpn | LSMeans, Lira | WORK.ADATA2 | 79.8456 | 0.5293 | 715 | 150.86 | <.0001 | 0.05 |

Least Squares Means Estimates

| Effect | Label | Lower | Upper | Exponentiated | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------|---------|---------|---------------|---------------------|---------------------|
| trtpn | LSMeans, IDegLira | 78.8664 | 80.3339 | 3.715E34 | 1.783E34 | 7.737E34 |
| trtpn | LSMeans, IDeg | 77.9680 | 80.0521 | 2.059E34 | 7.262E33 | 5.837E34 |
| trtpn | LSMeans, Lira | 78.8066 | 80.8847 | 4.748E34 | 1.68E34 | 1.342E35 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - IDeg | WORK.ADATA2 | 0.5901 | 0.6492 | 715 | 0.91 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.3636 | 0.05 | -0.6844 | 1.8646 | 1.8042 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - IDeg | 0.5044 | 6.4535 |

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=DIABPMEA

The Mixed Procedure

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value |
|--------|-------------------------------------|-------------|----------|----------------|-----|---------|
| trtpn | Treatment contrast, IDegLira - Lira | WORK.ADATA2 | -0.2455 | 0.6479 | 715 | -0.38 |

Least Squares Means Estimates

| Effect | Label | Pr > t | Alpha | Lower | Upper | Exponentiated |
|--------|-------------------------------------|---------|-------|---------|--------|---------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.7049 | 0.05 | -1.5175 | 1.0265 | 0.7823 |

Least Squares Means Estimates

| Effect | Label | Exponentiated Lower | Exponentiated Upper |
|--------|-------------------------------------|---------------------|---------------------|
| trtpn | Treatment contrast, IDegLira - Lira | 0.2193 | 2.7913 |

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=DIABPMEA

The Mixed Procedure

Model Information

| | |
|---------------------------|-------------|
| Data Set | WORK.ADATA2 |
| Dependent Variable | CHG |
| Covariance Structure | Diagonal |
| Estimation Method | REML |
| Residual Variance Method | Profile |
| Fixed Effects SE Method | Model-Based |
| Degrees of Freedom Method | Residual |

Class Level Information

| Class | Levels | Values |
|---------|--------|---------------------------|
| trtpn | 3 | 1 2 3 |
| PREOAD2 | 2 | Metformin Metformin + OAD |

Dimensions

| | |
|-----------------------|-----|
| Covariance Parameters | 1 |
| Columns in X | 7 |
| Columns in Z | 0 |
| Subjects | 1 |
| Max Obs per Subject | 720 |

Number of Observations

| | |
|---------------------------------|-----|
| Number of Observations Read | 720 |
| Number of Observations Used | 720 |
| Number of Observations Not Used | 0 |

Covariance Parameter Estimates

| Cov Parm | Estimate |
|----------|----------|
| Residual | 50.4183 |

Fit Statistics

| | |
|--------------------------|--------|
| -2 Res Log Likelihood | 4864.5 |
| AIC (Smaller is Better) | 4866.5 |
| AICC (Smaller is Better) | 4866.5 |
| BIC (Smaller is Better) | 4871.0 |

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Estimate | Standard Error | DF | t Value | Pr > t | Alpha |
|-----------|------------------------------------|-------------------------------------|----------|----------------|-----|---------|---------|-------|
| Intercept | | | 33.7874 | 2.3740 | 715 | 14.23 | <.0001 | 0.05 |
| trtpn | | 1 | -0.2455 | 0.6479 | 715 | -0.38 | 0.7049 | 0.05 |
| trtpn | | 2 | -0.8356 | 0.7496 | 715 | -1.11 | 0.2653 | 0.05 |
| trtpn | | 3 | 0 | | | | | |
| PREOAD2 | Metformin | | 0.6531 | 0.5681 | 715 | 1.15 | 0.2507 | 0.05 |
| PREOAD2 | Metformin + OAD | | 0 | | | | | |
| BASE | | | -0.4265 | 0.02907 | 715 | -14.67 | <.0001 | 0.05 |

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set

Parameter Code=DIABPMEA

The Mixed Procedure

Solution for Fixed Effects

| Effect | Pre Trial anti-Diabetic treatment2 | Planned Treatment for Period 01 (N) | Lower | Upper |
|-----------|------------------------------------|-------------------------------------|---------|---------|
| Intercept | | | 29.1266 | 38.4483 |
| trtpn | | 1 | -1.5175 | 1.0265 |
| trtpn | | 2 | -2.3072 | 0.6360 |
| trtpn | | 3 | | |
| PREOAD2 | Metformin | | -0.4622 | 1.7685 |
| PREOAD2 | Metformin + OAD | | | |
| BASE | | | -0.4835 | -0.3694 |

Type 3 Tests of Fixed Effects

| Effect | Num DF | Den DF | F Value | Pr > F |
|---------|--------|--------|---------|--------|
| trtpn | 2 | 715 | 0.67 | 0.5102 |
| PREOAD2 | 1 | 715 | 1.32 | 0.2507 |
| BASE | 1 | 715 | 215.17 | <.0001 |

Least Squares Means Estimates

| Effect | Label | Margins | Estimate | Standard Error | DF | t Value | Pr > t |
|--------|--------------------------------|-------------|----------|----------------|-----|---------|---------|
| trtpn | Change from baseline, IDegLira | WORK.ADATA2 | -0.3360 | 0.3737 | 715 | -0.90 | 0.3690 |
| trtpn | Change from baseline, IDeg | WORK.ADATA2 | -0.9261 | 0.5308 | 715 | -1.74 | 0.0815 |
| trtpn | Change from baseline, Lira | WORK.ADATA2 | -0.09047 | 0.5293 | 715 | -0.17 | 0.8643 |

Least Squares Means Estimates

| Effect | Label | Alpha | Lower | Upper |
|--------|--------------------------------|-------|---------|--------|
| trtpn | Change from baseline, IDegLira | 0.05 | -1.0697 | 0.3978 |
| trtpn | Change from baseline, IDeg | 0.05 | -1.9681 | 0.1160 |
| trtpn | Change from baseline, Lira | 0.05 | -1.1295 | 0.9486 |