

Cover Page for Statistical Analysis Plan

Sponsor name:	Novo Nordisk A/S
NCT number	NCT03175120
Sponsor trial ID:	NN9068-4166
Official title of study:	A trial comparing the efficacy and safety of insulin degludec/liraglutide and insulin degludec in combination with metformin in Chinese subjects with type 2 diabetes mellitus inadequately controlled with basal insulin therapy and metformin ± one other OAD. DUAL™ II China
Document date:	23 January 2020

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

16.1.9 Documentation of statistical methods

List of contents

Statistical analysis plan.....	Link
Statistical documentation.....	Link

Statistical Analysis Plan

Trial ID: NN9068-4166

A trial comparing the efficacy and safety of insulin degludec/liraglutide and insulin degludec in combination with metformin in Chinese subjects with type 2 diabetes mellitus inadequately controlled with basal insulin therapy and metformin \pm one other OAD

Author:



Table of contents

	Page
Table of contents	2
List of abbreviations	3
1 Introduction	4
1.1 Trial information	4
1.2 Scope of the statistical analysis plan	4
2 Statistical considerations	4
2.1 Sample size calculation	5
2.2 Definition of analysis sets.....	6
2.3 Primary endpoint.....	7
2.3.1 Sensitivity analysis	7
2.4 Secondary endpoints	8
2.4.1 Confirmatory secondary endpoints	8
2.4.2 Supportive secondary endpoints	10
2.4.2.1 Efficacy endpoints.....	10
2.4.2.2 Safety endpoints.....	12
3 Changes to the statistical analyses planned in the protocol.....	18
4 References	19

List of abbreviations

ADA	American Diabetes Association
AE	adverse event
ANCOVA	analysis of covariance
BG	blood glucose
BMI	body mass index
CAS	completer analysis set
CTR	clinical trial report
ECG	electrocardiogram
EOT	End of treatment
ET	End of treatment
FAS	full analysis set
FDA	U.S. Food and Drug Administration
FPG	fasting plasma glucose
HbA _{1c}	glycosylated haemoglobin
HDL	high density lipoprotein
HOMA- β	homeostatic model assessment
IDegLira	insulin degludec/liraglutide
IDeg	insulin degludec
ITT	intention-to-treat
LDL	low density lipoprotein
LLOQ	lower limit of quantification
LOCF	Last Observation Carried Forward
SAE	serious adverse event
SAP	statistical analysis plan
SAS	safety analysis set
SD	standard deviation
SMPG	self-measured plasma glucose
T2DM	type 2 diabetes mellitus
TEAEs	treatment emergent adverse events
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 two-arm, double-blind, multi-centre, treat-to-target (TTT) trial in Chinese subjects with T2DM inadequately controlled with basal insulin therapy and metformin \pm one other OAD: α -glucosidase inhibitors (AGI), sulphonylureas (SU), glinides or thiazolidinediones (TZD). The trial is comparing efficacy and safety of insulin degludec/liraglutide (IDegLira) versus insulin degludec (IDeg) both 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 (06-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 performed 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 antidiabetic treatment (basal insulin and metformin or basal insulin, metformin and other OAD(s)) as fixed factors and the corresponding baseline value as a 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 superiority of IDegLira vs. IDeg in controlling glycaemia in Chinese subjects with T2DM after 26 weeks of treatment. This is done by comparing

the difference in change from baseline in HbA_{1c} after 26 weeks of treatment to a superiority margin of 0.0% for IDegLira vs. IDeg.

Superiority in the primary endpoint for IDegLira versus IDeg will be considered confirmed if the upper bound of the two-sided 95% confidence interval for the estimated mean treatment difference in change from baseline in HbA_{1c} (for IDegLira - IDeg) is strictly below 0% or equivalently if the p-value for the two-sided test of

$$H_0 D=0 \text{ against } H_A D \neq 0,$$

is less than 5% and $D < 0$, where D is the estimated treatment difference. 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% (1-sided).

The sample size is determined using a t-statistic under the assumption of a two-sided test of size 5%, a mean difference in treatment of - 0.4%, and a standard deviation of $SD=1.2\%$. It is also assumed that 15% of the randomised subjects will be excluded from the PP analysis set. Superiority will be investigated for both the FAS and the PP analysis set in line with the Committee for Proprietary Medicinal Products (CPMP) Points to Consider². The above assumptions are based on experience from the phase 3a development programmes for IDegLira and IDeg. From these assumptions and based on a 2:1 randomisation the sample size is set to 300 subjects in the IDegLira arm and 150 subjects in the IDeg arm; in total 450 subjects will be randomised. This will ensure a power of 91.4% for confirming the primary objective in the full analysis set. Reducing the mean difference to -0.35% yields a power of 83%.

2.2 Definition of analysis sets

The following analysis sets are defined in accordance with the ICH-E9 guidance³.

- **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, previous antidiabetic treatment (basal insulin and metformin or basal insulin, metformin and other OAD(s)) as fixed effects and baseline HbA_{1c} as covariate. Missing values after 26 weeks of treatment will be imputed LOCF using HbA_{1c} values at and after baseline.

Superiority of IDegLira vs. IDeg 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. Analysis based on the PP analysis set will be regarded as sensitivity analysis.

2.3.1 Sensitivity analysis

The primary efficacy 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 antidiabetic treatment as fixed factors and baseline HbA_{1c} as a covariate. Interactions between visit and all factors and the covariate are also included in the model.

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

Further, a pattern mixture model approach, mimicking an intention-to-treat scenario will be applied. The imputation in the IDegLira arm will be based on IDeg values. It will be done as follows:

- In the first step intermittent missing values are imputed using a Markov Chain Monte Carlo 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 anti-diabetic treatment as fixed factors, and baseline HbA1c as covariates is fitted to the change in HbA1c from baseline to 4 weeks (V10) for the IDeg group only. The estimated parameters, and their variances, from this model are used to impute missing values at 4 weeks for subjects in IDeg and IDegLira treatment groups, based on previous anti-diabetic treatment and HbA1c at baseline.
- In the third step, for each of the 1000 copies of the dataset, missing HbA1c values at 8 weeks (V15) 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 HbA1c values at baseline and 4 weeks as covariates, fitted to the IDeg 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 (V33).
- 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 anti-diabetic treatment as fixed factors and baseline HbA1c value as a covariate.

The estimates and standard deviations for data sets are pooled to one estimate and associated standard deviation using Rubin's rule⁴. From these pooled estimates the confidence interval for the treatment differences and the associated p-value are calculated.

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 superiority of IDegLira vs. IDeg with regards to the primary endpoint is 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 antidiabetic treatment (basal insulin and metformin or basal insulin, metformin and other OAD(s)) as fixed effect and baseline weight as covariate.

The similar sensitivity analyses as specified for the primary endpoint (ANCOVA on the PP analysis set and CAS, MMRM and the pattern mixture model) 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

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

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

The 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 antidiabetic 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]) will be imputed using a multiple imputation technique⁵, and

assuming that all subjects have an event rate in the period before and after withdrawal corresponding to the event rate in the comparator group (IDeg). This 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 (IDeg) 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 comparator (IDeg). Multiple copies (1000 copies) of a complete data set are generated by sampling from the estimated distribution.
- In the third step, 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.
- In the fourth step, the estimates and standard deviations for the 1000 data sets are pooled to one estimate and associated standard deviation using Rubin's rule⁴. From these pooled estimates the confidence interval for the treatment ratio and the associated p-value are calculated.

2.4.2 Supportive secondary endpoints

2.4.2.1 Efficacy endpoints

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 antidiabetic treatment as fixed factors and baseline HbA_{1c} value and insulin dose at screening as covariates.

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 antidiabetic 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 antidiabetic 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 antidiabetic 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 antidiabetic 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, low density lipoprotein cholesterol (LDL cholesterol), high density lipoprotein cholesterol (HDL cholesterol), very low density lipoprotein 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 (SMPG) 9-point profile

Three endpoints from the 9 point SMPG 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 PG 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 linear mixed effect model will be fitted to the 9-point SMPG profile data. The model will include treatment, previous antidiabetic treatment, time, the interaction between treatment and time and the interaction between previous antidiabetic 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 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-treatment emergent adverse events with onset date before the first day of exposure to randomised treatment will be presented. A listing will also be presented for non-treatment emergent adverse events 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.

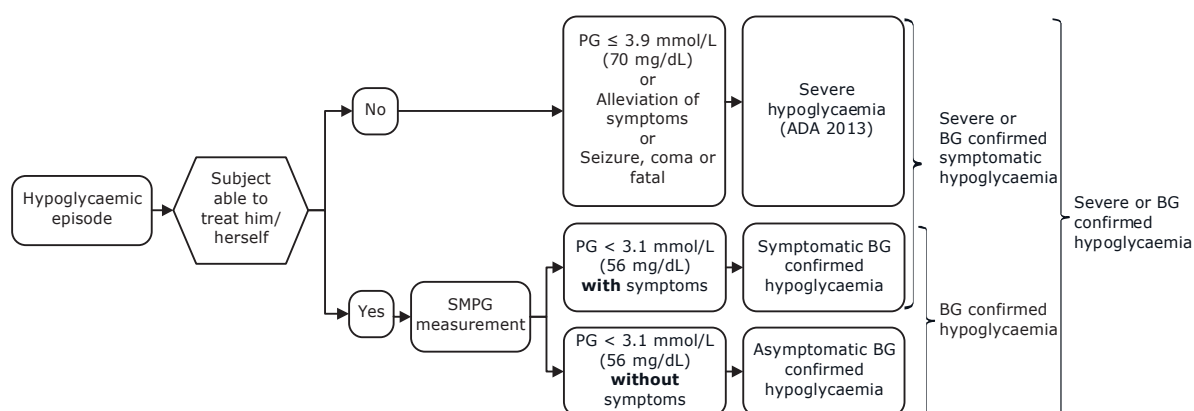
Hypoglycaemic episodes are classified according to the Novo Nordisk classification of hypoglycaemia (see [Figure 1](#)) and the ADA classification of hypoglycaemia (see [Figure 2](#)).

Novo Nordisk classification of hypoglycaemia

In normal physiology, symptoms of hypoglycaemia occur below a plasma glucose level of 3.1 mmol/L.⁶ 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 1](#)) in addition to the ADA classification (see [Figure 2](#))

- Severe or BG confirmed symptomatic hypoglycaemia: An episode that is severe according to the ADA classification⁷ 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 classification⁷ 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

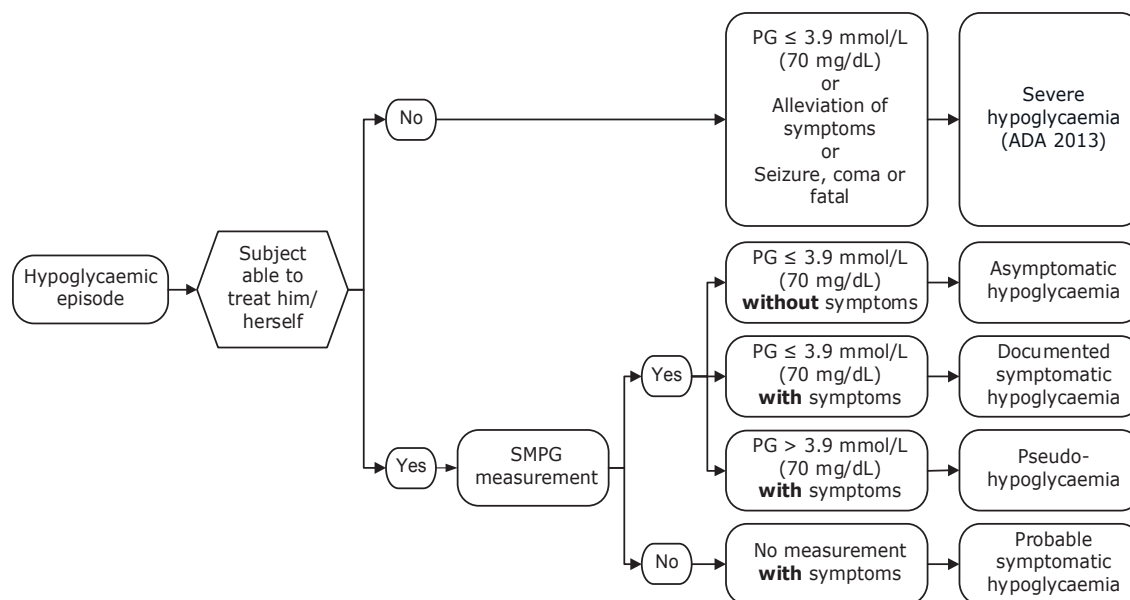
BG: blood glucose PG: plasma glucose SMPG: Self-measured plasma glucose

Figure 1 Novo Nordisk classification of hypoglycaemia

ADA classification of hypoglycaemia⁷

- 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 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 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 antidiabetic treatment as fixed factor.

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, funduscopy or fundus photography 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 findings in the physical examination evaluation at screening will be presented as listings. 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 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 will apply in the evaluation of the result:

- If the amylase or lipase baseline (at screening) value is $> 3xUNR$ the information were 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 < UNR to persistently \geq UNR
 - From < UNR to persistently \geq 1.5 UNR
 - From < UNR to persistently \geq 20 ng/L
 - From < UNR to persistently \geq 50 ng/L
 - From < 20 ng/L to persistently \geq 20 ng/L
 - From < 50 ng/L to persistently \geq 50 ng/L
- Incidental (at least one post baseline measurements)
 - From < UNR to \geq UNR
 - From < UNR to \geq 1.5 UNR
 - From < UNR to \geq 20 ng/L
 - From < UNR to \geq 50 ng/L
 - From < 20 ng/L to \geq 20 ng/L
 - From < 50 ng/L to \geq 50 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 \geq 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 \geq 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.

Antibody measurements will be listed by subject and visit together with associated age, sex, BMI, HbA_{1c} and dose

3 Changes to the statistical analyses planned in the protocol

- Additional sensitivity analysis added to use pattern mixture model to evaluate the sensitivity of using LOCF for primary endpoint HbA_{1c}
- Sensitivity analyses for confirmatory secondary endpoints have been added.
- One minor change regarding the analysis model to the supportive secondary endpoint of 9-point self-measured plasma glucose has been made

4 References

-
- ¹ U.S. Department of Health and Human Services, Food and Drug Administration. Guidance for Industry. Diabetes Mellitus: Developing Drugs and Therapeutic Biologics for Treatment and Prevention, Draft Guidance. 2008.
- ² European Medicines Agency. Committee for Proprietary Medical Products (CPMP): Points to consider on switching between superiority and non-inferiority (CPMP/EWP/482/99). EMEA 2000. 2000.
- ³ International Conference on Harmonisation. ICH Harmonised Tripartite Guideline E9. Statistical Principles for Clinical Trials. 5 Feb 1998.
- ⁴ Little RJA, Rubin D.B. Statistical analysis with missing data. New York: John Wiley & Sons, 1987.
- ⁵ Keene ONe. Missing data sensitivity analysis for recurrent event data using controlled imputation. Pharm Stat 2014; 13:258-264.
- ⁶ 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.
- ⁷ 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 - appendix	4
2: HbA1c after 26 weeks of treatment – change from baseline – confirmatory statistical analysis – full analysis set - appendix	7
3: HbA1c after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – PP analysis set - appendix	17
4: HbA1c after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – completer analysis set - appendix	27
5: HbA1c after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – MMRM – full analysis set - appendix	37
6: HbA1c after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – conditional multiple imputation – full analysis set - appendix	57
7: Responder for HbA1c treatment target – supportive statistical analysis – full analysis set	67
8: Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes – supportive statistical analysis – full analysis set	71
9: Responder for HbA1c treatment target without weight gain – supportive statistical analysis – full analysis set	75
10: Responder for HbA1c treatment target without treatment emergent severe or BG confirmed hypoglycaemic episodes and weight gain – supportive statistical analysis – full analysis set	81
11: Body weight after 26 weeks of treatment – change from baseline – confirmatory statistical analysis – full analysis set - appendix	87
12: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – PP analysis set - appendix	97
13: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – completer analysis set - appendix	107
14: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – MMRM – full analysis set - appendix	117
15: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – conditional multiple imputation – full analysis set - appendix	137
16: Waist circumference after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix	147
17: Fasting plasma glucose after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix	152
18: 9-point self-measured plasma glucose profile after 26 weeks of treatment – supportive statistical analysis – full analysis set	162
19: Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix	204

20: Prandial increment after 26 weeks of treatment – 9-point self-measured plasma glucose profile – change from baseline – supportive statistical analysis – full analysis set - appendix	214
21: Fasting insulin after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	254
22: Fasting C-peptide after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	257
23: Fasting glucagon after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	263
24: HOMA-B after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix....	266
25: HDL cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	269
26: LDL cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	275
27: VLDL cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	281
28: Triglycerides after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	287
29: Total cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	293
30: Free fatty acid after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix	299
31: Hypoglycaemic episodes – treatment emergent – confirmatory statistical analysis – full analysis set ...	305
32: Hypoglycaemic episodes – treatment emergent – statistical sensitivity analysis – multiple imputation – full analysis set.....	307
33: Hypoglycaemic episodes – treatment emergent – supportive statistical analysis – full analysis set	310
34: Nocturnal hypoglycaemic episodes – treatment emergent – supportive statistical analysis – full analysis set.....	313
35: Pulse after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix	320
36: Systolic blood pressure after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix	325
37: Diastolic blood pressure after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix	330

NN9068
NN9068-4166
Clinical Trial Report
Statistical document

~~CONFIDENTIAL~~

Date:	22 January 2020	Novo Nordisk
Version:	1.0	
Status:	Final	
Page:	3 of 334	

Statistical documentation

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

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
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 7
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 450

Number of Observations

Number of Observations Read 453
 Number of Observations Used 450
 Number of Observations Not Used 3

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	109.52

Fit Statistics

-2 Res Log Likelihood 3384.2
 AIC (Smaller is Better) 3386.2
 AICC (Smaller is Better) 3386.2
 BIC (Smaller is Better) 3390.3

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	7.9327	4.2569	445	1.86
trtpn		1	-3.3593	1.0472	445	-3.21
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-1.0335	0.9944	445	-1.04
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
INSSCR			0.4191	0.08246	445	5.08

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

Parameter Code=TOTDDAC

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
HBAlCBL			2.1936	0.4169	445	5.26

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0631	0.05
trtpn		1	0.0014	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.2992	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
INSSCR			<.0001	0.05
HBAlCBL			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-0.4334	16.2989
trtpn		1	-5.4174	-1.3013
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-2.9879	0.9209
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
INSSCR			0.2571	0.5812
HBAlCBL			1.3742	3.0130

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	10.29	0.0014
PREAD	1	445	1.08	0.2992
INSSCR	1	445	25.83	<.0001
HBAlCBL	1	445	27.68	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	34.2145	0.6057	445	56.49	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	37.5739	0.8529	445	44.05	<.0001	0.05

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

Parameter Code=TOTDDAC

The Mixed Procedure

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	33.0242	35.4049	7.231E14	2.199E14	2.378E15
trtpn	LSMeans, IDeg	35.8976	39.2501	2.08E16	3.892E15	1.112E17

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-3.3593	1.0472	445	-3.21

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0014	0.05	-5.4174	-1.3013	0.03476

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.004439	0.2722

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.7569

Fit Statistics

-2 Res Log Likelihood 1171.1
 AIC (Smaller is Better) 1173.1
 AICC (Smaller is Better) 1173.1
 BIC (Smaller is Better) 1177.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	4.8895	0.3187	449	15.34
TRTPN		1	-0.9186	0.08674	449	-10.59
TRTPN		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2401	0.08191	449	-2.93
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.3580	0.03449	449	10.38

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

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
TRTPN		1	<.0001	0.05
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		0.0036	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			4.2631	5.5159
TRTPN		1	-1.0891	-0.7481
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4010	-0.07910
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.2902	0.4258

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	1	449	112.15	<.0001
PREAD	1	449	8.59	0.0036
BASE	1	449	107.71	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
TRTPN	LSMeans, IDegLira	WORK.ADATA2	7.0585	0.05007	449	140.98	<.0001	0.05
TRTPN	LSMeans, IDeg	WORK.ADATA2	7.9771	0.07082	449	112.65	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	LSMeans, IDegLira	6.9601	7.1569	1162.68	1053.72	1282.90
TRTPN	LSMeans, IDeg	7.8379	8.1162	2913.40	2534.89	3348.43

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
TRTPN	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.9186	0.08674	449	-10.59

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

Parameter Code=C64849B

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
TRTPN	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-1.0891	-0.7481	0.3991

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
TRTPN	Treatment contrast, IDegLira - IDeg	0.3365	0.4733

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	90.4255

Fit Statistics

-2 Res Log Likelihood	3323.4
AIC (Smaller is Better)	3325.4
AICC (Smaller is Better)	3325.4
BIC (Smaller is Better)	3329.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			38.3549	2.7080	449	14.16
TRTPN		1	-10.0402	0.9481	449	-10.59
TRTPN		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.6239	0.8952	449	-2.93
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.3580	0.03449	449	10.38

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

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
TRTPN		1	<.0001	0.05
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		0.0036	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			33.0330	43.6767
TRTPN		1	-11.9034	-8.1770
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		-4.3832	-0.8645
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.2902	0.4258

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	1	449	112.15	<.0001
PREAD	1	449	8.59	0.0036
BASE	1	449	107.71	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
TRTPN	LSMeans, IDegLira	WORK.ADATA2	53.6492	0.5473	449	98.03	<.0001	0.05
TRTPN	LSMeans, IDeg	WORK.ADATA2	63.6894	0.7740	449	82.29	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	LSMeans, IDegLira	52.5737	54.7247	1.993E23	6.799E22	5.843E23
TRTPN	LSMeans, IDeg	62.1683	65.2106	4.571E27	9.985E26	2.092E28

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
TRTPN	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-10.0402	0.9481	449	-10.59

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

Parameter Code=HBA1CONV

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
TRTPN	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-11.9034	-8.1770	0.000044

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
TRTPN	Treatment contrast, IDegLira - IDeg	6.767E-6	0.000281

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.7569

Fit Statistics

-2 Res Log Likelihood	1171.1
AIC (Smaller is Better)	1173.1
AICC (Smaller is Better)	1173.1
BIC (Smaller is Better)	1177.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			4.8895	0.3187	449	15.34
TRTPN		1	-0.9186	0.08674	449	-10.59
TRTPN		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2401	0.08191	449	-2.93
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.6420	0.03449	449	-18.61

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

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
TRTPN		1	<.0001	0.05
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		0.0036	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			4.2631	5.5159
TRTPN		1	-1.0891	-0.7481
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4010	-0.07910
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.7098	-0.5742

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	1	449	112.15	<.0001
PREAD	1	449	8.59	0.0036
BASE	1	449	346.39	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
TRTPN	Change from baseline, IDegLira	WORK.ADATA2	-1.8843	0.05007	449	-37.64	<.0001
TRTPN	Change from baseline, IDeg	WORK.ADATA2	-0.9658	0.07082	449	-13.64	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
TRTPN	Change from baseline, IDegLira	0.05	-1.9827	-1.7859
TRTPN	Change from baseline, IDeg	0.05	-1.1049	-0.8266

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	90.4255

Fit Statistics

-2 Res Log Likelihood	3323.4
AIC (Smaller is Better)	3325.4
AICC (Smaller is Better)	3325.4
BIC (Smaller is Better)	3329.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			38.3549	2.7080	449	14.16
TRTPN		1	-10.0402	0.9481	449	-10.59
TRTPN		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.6239	0.8952	449	-2.93
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.6420	0.03449	449	-18.61

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

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
TRTPN		1	<.0001	0.05
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		0.0036	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			33.0330	43.6767
TRTPN		1	-11.9034	-8.1770
TRTPN		2		
PREAD	BASAL INSULIN + METFORMIN		-4.3832	-0.8645
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.7098	-0.5742

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	1	449	112.15	<.0001
PREAD	1	449	8.59	0.0036
BASE	1	449	346.39	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
TRTPN	Change from baseline, IDegLira	WORK.ADATA2	-20.5959	0.5473	449	-37.64	<.0001
TRTPN	Change from baseline, IDeg	WORK.ADATA2	-10.5556	0.7740	449	-13.64	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
TRTPN	Change from baseline, IDegLira	0.05	-21.6714	-19.5204
TRTPN	Change from baseline, IDeg	0.05	-12.0768	-9.0345

3: HbA1c after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – PP analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.7326

Fit Statistics

-2 Res Log Likelihood	1100.6
AIC (Smaller is Better)	1102.6
AICC (Smaller is Better)	1102.6
BIC (Smaller is Better)	1106.6

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			4.9698	0.3237	427	15.35
trtan		1	-0.9065	0.08773	427	-10.33
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2699	0.08260	427	-3.27
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.3456	0.03506	427	9.86

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

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtan		1	<.0001	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.0012	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			4.3335	5.6061
trtan		1	-1.0790	-0.7341
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4322	-0.1075
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.2767	0.4145

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	106.78	<.0001
PREAD	1	427	10.67	0.0012
BASE	1	427	97.16	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtan	LSMeans, IDegLira	WORK.ADATA2	7.0308	0.05035	427	139.64	<.0001	0.05
trtan	LSMeans, IDeg	WORK.ADATA2	7.9373	0.07183	427	110.50	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtan	LSMeans, IDegLira	6.9318	7.1298	1130.93	1024.37	1248.58
trtan	LSMeans, IDeg	7.7961	8.0785	2799.86	2431.19	3224.45

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtan	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.9065	0.08773	427	-10.33

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

Parameter Code=C64849B

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtan	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-1.0790	-0.7341	0.4039

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtan	Treatment contrast, IDegLira - IDeg	0.3399	0.4799

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	87.5168

Fit Statistics

-2 Res Log Likelihood	3147.7
AIC (Smaller is Better)	3149.7
AICC (Smaller is Better)	3149.7
BIC (Smaller is Better)	3153.8

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			38.9418	2.7492	427	14.16
trtan		1	-9.9084	0.9589	427	-10.33
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.9498	0.9029	427	-3.27
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.3456	0.03506	427	9.86

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

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtan		1	<.0001	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.0012	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			33.5380	44.3455
trtan		1	-11.7931	-8.0237
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-4.7244	-1.1752
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.2767	0.4145

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	106.78	<.0001
PREAD	1	427	10.67	0.0012
BASE	1	427	97.16	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtan	LSMeans, IDegLira	WORK.ADATA2	53.3466	0.5503	427	96.94	<.0001	0.05
trtan	LSMeans, IDeg	WORK.ADATA2	63.2550	0.7851	427	80.57	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtan	LSMeans, IDegLira	52.2649	54.4283	1.473E23	4.993E22	4.344E23
trtan	LSMeans, IDeg	61.7118	64.7982	2.96E27	6.325E26	1.385E28

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtan	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-9.9084	0.9589	427	-10.33

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

Parameter Code=HBA1CONV

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtan	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-11.7931	-8.0237	0.000050

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtan	Treatment contrast, IDegLira - IDeg	7.557E-6	0.000328

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.7326

Fit Statistics

-2 Res Log Likelihood	1100.6
AIC (Smaller is Better)	1102.6
AICC (Smaller is Better)	1102.6
BIC (Smaller is Better)	1106.6

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			4.9698	0.3237	427	15.35
trtan		1	-0.9065	0.08773	427	-10.33
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2699	0.08260	427	-3.27
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.6544	0.03506	427	-18.66

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

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtan		1	<.0001	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.0012	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			4.3335	5.6061
trtan		1	-1.0790	-0.7341
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4322	-0.1075
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.7233	-0.5855

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	106.78	<.0001
PREAD	1	427	10.67	0.0012
BASE	1	427	348.31	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtan	Change from baseline, IDegLira	WORK.ADATA2	-1.9251	0.05035	427	-38.23	<.0001
trtan	Change from baseline, IDeg	WORK.ADATA2	-1.0186	0.07183	427	-14.18	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtan	Change from baseline, IDegLira	0.05	-2.0241	-1.8262
trtan	Change from baseline, IDeg	0.05	-1.1598	-0.8774

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	87.5168

Fit Statistics

-2 Res Log Likelihood	3147.7
AIC (Smaller is Better)	3149.7
AICC (Smaller is Better)	3149.7
BIC (Smaller is Better)	3153.8

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			38.9418	2.7492	427	14.16
trtan		1	-9.9084	0.9589	427	-10.33
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.9498	0.9029	427	-3.27
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.6544	0.03506	427	-18.66

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

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtan		1	<.0001	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.0012	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			33.5380	44.3455
trtan		1	-11.7931	-8.0237
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-4.7244	-1.1752
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.7233	-0.5855

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	106.78	<.0001
PREAD	1	427	10.67	0.0012
BASE	1	427	348.31	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtan	Change from baseline, IDegLira	WORK.ADATA2	-21.0416	0.5503	427	-38.23	<.0001
trtan	Change from baseline, IDeg	WORK.ADATA2	-11.1332	0.7851	427	-14.18	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtan	Change from baseline, IDegLira	0.05	-22.1233	-19.9599
trtan	Change from baseline, IDeg	0.05	-12.6764	-9.5900

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	429

Number of Observations

Number of Observations Read	429
Number of Observations Used	429
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	0.7214

Fit Statistics

-2 Res Log Likelihood	1089.0
AIC (Smaller is Better)	1091.0
AICC (Smaller is Better)	1091.0
BIC (Smaller is Better)	1095.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	4.9165	0.3212	425	15.31
trtpn		1	-0.8833	0.08766	425	-10.08
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2517	0.08217	425	-3.06
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.3478	0.03473	425	10.01

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

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.0023	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			4.2851	5.5479
trtpn		1	-1.0556	-0.7110
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4132	-0.09016
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.2795	0.4160

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	101.54	<.0001
PREAD	1	425	9.38	0.0023
BASE	1	425	100.29	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	7.0285	0.04988	425	140.90	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	7.9118	0.07206	425	109.79	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	6.9304	7.1265	1128.32	1022.95	1244.55
trtpn	LSMeans, IDeg	7.7701	8.0534	2729.27	2368.82	3144.55

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.8833	0.08766	425	-10.08

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

Parameter Code=C64849B

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-1.0556	-0.7110	0.4134

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.3480	0.4912

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	429

Number of Observations

Number of Observations Read	429
Number of Observations Used	429
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	86.1783

Fit Statistics

-2 Res Log Likelihood	3126.5
AIC (Smaller is Better)	3128.5
AICC (Smaller is Better)	3128.5
BIC (Smaller is Better)	3132.6

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			38.4099	2.7306	425	14.07
trtpn		1	-9.6545	0.9581	425	-10.08
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.7507	0.8981	425	-3.06
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.3478	0.03473	425	10.01

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

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.0023	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			33.0428	43.7771
trtpn		1	-11.5377	-7.7713
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-4.5160	-0.9855
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.2795	0.4160

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	101.54	<.0001
PREAD	1	425	9.38	0.0023
BASE	1	425	100.29	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	53.3214	0.5452	425	97.80	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	62.9758	0.7876	425	79.96	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	52.2497	54.3930	1.436E23	4.918E22	4.194E23
trtpn	LSMeans, IDeg	61.4277	64.5240	2.239E27	4.761E26	1.053E28

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-9.6545	0.9581	425	-10.08

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

Parameter Code=HBA1CONV

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-11.5377	-7.7713	0.000064

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	9.756E-6	0.000422

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	429

Number of Observations

Number of Observations Read	429
Number of Observations Used	429
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	0.7214

Fit Statistics

-2 Res Log Likelihood	1089.0
AIC (Smaller is Better)	1091.0
AICC (Smaller is Better)	1091.0
BIC (Smaller is Better)	1095.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			4.9165	0.3212	425	15.31
trtpn		1	-0.8833	0.08766	425	-10.08
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2517	0.08217	425	-3.06
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.6522	0.03473	425	-18.78

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

Parameter Code=C64849B

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.0023	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			4.2851	5.5479
trtpn		1	-1.0556	-0.7110
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4132	-0.09016
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.7205	-0.5840

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	101.54	<.0001
PREAD	1	425	9.38	0.0023
BASE	1	425	352.70	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-1.9282	0.04988	425	-38.65	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	-1.0449	0.07206	425	-14.50	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-2.0262	-1.8301
trtpn	Change from baseline, IDeg	0.05	-1.1865	-0.9032

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 429

Number of Observations

Number of Observations Read 429
 Number of Observations Used 429
 Number of Observations Not Used 0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	86.1783

Fit Statistics

-2 Res Log Likelihood 3126.5
 AIC (Smaller is Better) 3128.5
 AICC (Smaller is Better) 3128.5
 BIC (Smaller is Better) 3132.6

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			38.4099	2.7306	425	14.07
trtpn		1	-9.6545	0.9581	425	-10.08
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.7507	0.8981	425	-3.06
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.6522	0.03473	425	-18.78

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

Parameter Code=HBA1CONV

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.0023	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			33.0428	43.7771
trtpn		1	-11.5377	-7.7713
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-4.5160	-0.9855
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.7205	-0.5840

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	101.54	<.0001
PREAD	1	425	9.38	0.0023
BASE	1	425	352.70	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-21.0747	0.5452	425	-38.65	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	-11.4203	0.7876	425	-14.50	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-22.1464	-20.0031
trtpn	Change from baseline, IDeg	0.05	-12.9684	-9.8722

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

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	2	1 2
AVISITN	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

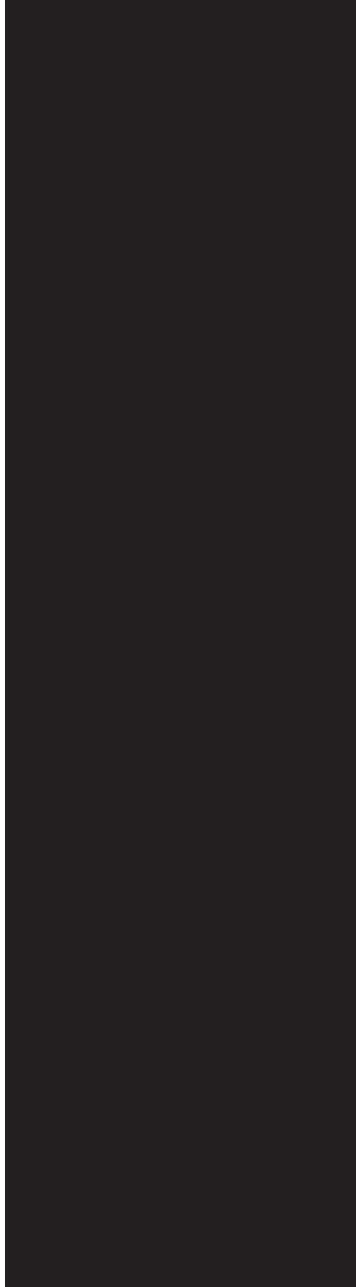
HbA1c after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM
- full analysis set - appendix

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

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	453	



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

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

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2595
Number of Observations Not Used	123

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

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

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	6180.47425772	
1	2	2415.05948115	0.00247120
2	1	2411.88149460	0.00009868
3	1	2411.76403647	0.00000020
4	1	2411.76380269	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	0.3328
UN(2,1)	SUBJID	0.3392
UN(2,2)	SUBJID	0.5343
UN(3,1)	SUBJID	0.2998
UN(3,2)	SUBJID	0.5436
UN(3,3)	SUBJID	0.6809
UN(4,1)	SUBJID	0.2578
UN(4,2)	SUBJID	0.4980
UN(4,3)	SUBJID	0.6498
UN(4,4)	SUBJID	0.7191
UN(5,1)	SUBJID	0.2311
UN(5,2)	SUBJID	0.4455
UN(5,3)	SUBJID	0.5985
UN(5,4)	SUBJID	0.6761
UN(5,5)	SUBJID	0.7336
UN(6,1)	SUBJID	0.2068
UN(6,2)	SUBJID	0.4124
UN(6,3)	SUBJID	0.5440
UN(6,4)	SUBJID	0.6102
UN(6,5)	SUBJID	0.6641
UN(6,6)	SUBJID	0.7317

Fit Statistics

-2 Res Log Likelihood	2411.8
AIC (Smaller is Better)	2453.8
AICC (Smaller is Better)	2454.1
BIC (Smaller is Better)	2540.2

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	3768.71	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN (AVISITN)	6	435	35.96	<.0001
PREAD (AVISITN)	6	432	2.36	0.0293
BASE (AVISITN)	6	433	213.91	<.0001

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

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	7.0309	0.05012	427.4	140.29	<.0001
TRT01PN (AVISITN)	LSMeans, IDeg	WORK.ANA_DATA	7.9479	0.07142	437.4	111.28	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
TRT01PN (AVISITN)	LSMeans, IDegLira	0.05	6.9324	7.1294
TRT01PN (AVISITN)	LSMeans, IDeg	0.05	7.8075	8.0883

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

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	2	1 2
AVISITN	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

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

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

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	453	



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

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

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2595
Number of Observations Not Used	123

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

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

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	18506.32350920	
1	2	14740.90873263	0.00056998
2	1	14737.73074608	0.00002280
3	1	14737.61328795	0.00000005
4	1	14737.61305417	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	39.7612
UN(2,1)	SUBJID	40.5209
UN(2,2)	SUBJID	63.8318
UN(3,1)	SUBJID	35.8164
UN(3,2)	SUBJID	64.9397
UN(3,3)	SUBJID	81.3416
UN(4,1)	SUBJID	30.8032
UN(4,2)	SUBJID	59.4989
UN(4,3)	SUBJID	77.6293
UN(4,4)	SUBJID	85.9110
UN(5,1)	SUBJID	27.6057
UN(5,2)	SUBJID	53.2163
UN(5,3)	SUBJID	71.5019
UN(5,4)	SUBJID	80.7653
UN(5,5)	SUBJID	87.6338
UN(6,1)	SUBJID	24.7005
UN(6,2)	SUBJID	49.2619
UN(6,3)	SUBJID	64.9837
UN(6,4)	SUBJID	72.8959
UN(6,5)	SUBJID	79.3406
UN(6,6)	SUBJID	87.4072

Fit Statistics

-2 Res Log Likelihood	14737.6
AIC (Smaller is Better)	14779.6
AICC (Smaller is Better)	14780.0
BIC (Smaller is Better)	14866.0

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	3768.71	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN (AVISITN)	6	435	35.96	<.0001
PREAD (AVISITN)	6	432	2.36	0.0293
BASE (AVISITN)	6	433	213.91	<.0001

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

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	53.3477	0.5478	427.4	97.39	<.0001
TRT01PN (AVISITN)	LSMeans, IDeg	WORK.ANA_DATA	63.3707	0.7806	437.4	81.18	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
TRT01PN (AVISITN)	LSMeans, IDegLira	0.05	52.2710	54.4243
TRT01PN (AVISITN)	LSMeans, IDeg	0.05	61.8365	64.9050

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

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	2	1 2
AVISITN	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

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

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

The Mixed Procedure

Class Level Information

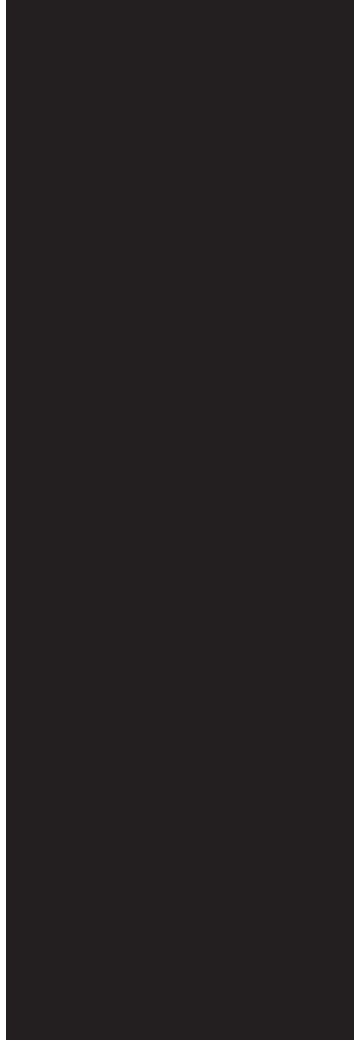
Class	Levels	Values
SUBJID	453	



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

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

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2595
Number of Observations Not Used	123

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

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

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	6180.47425772	
1	2	2415.05948115	0.00247120
2	1	2411.88149460	0.00009868
3	1	2411.76403647	0.00000020
4	1	2411.76380269	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	0.3328
UN(2,1)	SUBJID	0.3392
UN(2,2)	SUBJID	0.5343
UN(3,1)	SUBJID	0.2998
UN(3,2)	SUBJID	0.5436
UN(3,3)	SUBJID	0.6809
UN(4,1)	SUBJID	0.2578
UN(4,2)	SUBJID	0.4980
UN(4,3)	SUBJID	0.6498
UN(4,4)	SUBJID	0.7191
UN(5,1)	SUBJID	0.2311
UN(5,2)	SUBJID	0.4455
UN(5,3)	SUBJID	0.5985
UN(5,4)	SUBJID	0.6761
UN(5,5)	SUBJID	0.7336
UN(6,1)	SUBJID	0.2068
UN(6,2)	SUBJID	0.4124
UN(6,3)	SUBJID	0.5440
UN(6,4)	SUBJID	0.6102
UN(6,5)	SUBJID	0.6641
UN(6,6)	SUBJID	0.7317

Fit Statistics

-2 Res Log Likelihood	2411.8
AIC (Smaller is Better)	2453.8
AICC (Smaller is Better)	2454.1
BIC (Smaller is Better)	2540.2

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	3768.71	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN (AVISITN)	6	435	35.96	<.0001
PREAD (AVISITN)	6	432	2.36	0.0293
BASE (AVISITN)	6	433	65.36	<.0001

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

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	-1.9341	0.05012	427.4	-38.59
TRT01PN(AVISITN)	Change from baseline, IDeg	WORK.ANA_DATA	-1.0171	0.07142	437.4	-14.24

Least Squares Means Estimates

Effect	Label	Pr > t	Alpha	Lower	Upper
TRT01PN(AVISITN)	Change from baseline, IDegLira	<.0001	0.05	-2.0326	-1.8356
TRT01PN(AVISITN)	Change from baseline, IDeg	<.0001	0.05	-1.1574	-0.8767

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF
TRT01PN(AVISITN)	Treatment contrast, IDegLira - IDeg	WORK.ANA_DATA	-0.9170	0.08726	434.1

Least Squares Means Estimate

Effect	Label	t Value	Pr > t	Alpha	Lower	Upper
TRT01PN(AVISITN)	Treatment contrast, IDegLira - IDeg	-10.51	<.0001	0.05	-1.0885	-0.7455

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

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	2	1 2
AVISITN	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

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

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

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	453	



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

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

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2595
Number of Observations Not Used	123

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

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

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	18506.32350920	
1	2	14740.90873263	0.00056998
2	1	14737.73074608	0.00002280
3	1	14737.61328795	0.00000005
4	1	14737.61305417	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	39.7612
UN(2,1)	SUBJID	40.5209
UN(2,2)	SUBJID	63.8318
UN(3,1)	SUBJID	35.8164
UN(3,2)	SUBJID	64.9397
UN(3,3)	SUBJID	81.3416
UN(4,1)	SUBJID	30.8032
UN(4,2)	SUBJID	59.4989
UN(4,3)	SUBJID	77.6293
UN(4,4)	SUBJID	85.9110
UN(5,1)	SUBJID	27.6057
UN(5,2)	SUBJID	53.2163
UN(5,3)	SUBJID	71.5019
UN(5,4)	SUBJID	80.7653
UN(5,5)	SUBJID	87.6338
UN(6,1)	SUBJID	24.7005
UN(6,2)	SUBJID	49.2619
UN(6,3)	SUBJID	64.9837
UN(6,4)	SUBJID	72.8959
UN(6,5)	SUBJID	79.3406
UN(6,6)	SUBJID	87.4072

Fit Statistics

-2 Res Log Likelihood	14737.6
AIC (Smaller is Better)	14779.6
AICC (Smaller is Better)	14780.0
BIC (Smaller is Better)	14866.0

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	3768.71	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN (AVISITN)	6	435	35.96	<.0001
PREAD (AVISITN)	6	432	2.36	0.0293
BASE (AVISITN)	6	433	65.36	<.0001

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

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	-21.1395	0.5478	427.4	-38.59
TRT01PN(AVISITN)	Change from baseline, IDeg	WORK.ANA_DATA	-11.1164	0.7806	437.4	-14.24

Least Squares Means Estimates

Effect	Label	Pr > t	Alpha	Lower	Upper
TRT01PN(AVISITN)	Change from baseline, IDegLira	<.0001	0.05	-22.2161	-20.0628
TRT01PN(AVISITN)	Change from baseline, IDeg	<.0001	0.05	-12.6506	-9.5822

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF
TRT01PN(AVISITN)	Treatment contrast, IDegLira - IDeg	WORK.ANA_DATA	-10.0231	0.9538	434.1

Least Squares Means Estimate

Effect	Label	t Value	Pr > t	Alpha	Lower	Upper
TRT01PN(AVISITN)	Treatment contrast, IDegLira - IDeg	-10.51	<.0001	0.05	-11.8977	-8.1485

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

PARAMSORT=1 Parameter Code=C64849B Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000311	0.004942	0.005254	283778

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.063075	0.059339	0.999941

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.934431	0.072481	7.792370	8.076492	283778	7.884262	7.988346

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	109.47	<.0001

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

PARAMSORT=1 Parameter Code=C64849B Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000110	0.002470	0.002580	550770

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.044484	0.042592	0.999957

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	7.051117	0.050797	6.951557	7.150676	550770	7.011871	7.088745

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	138.81	<.0001

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

PARAMSORT=2 Parameter Code=HBA1CONV Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.037201	0.590373	0.627611	283778

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.063075	0.059339	0.999941

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	63.223331	0.792219	61.67060	64.77606	283778	62.674980	63.812625

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	79.81	<.0001

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

PARAMSORT=2 Parameter Code=HBA1CONV Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.013115	0.295126	0.308254	550770

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.044484	0.042592	0.999957

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	53.568705	0.555206	52.48052	54.65689	550770	53.139750	53.979986

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	96.48	<.0001

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

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

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000311	0.004942	0.005254	283778

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.063075	0.059339	0.999941

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.008395	0.072481	-1.15046	-0.86633	283778	-1.058564	-0.954479

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-13.91	<.0001

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

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

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000110	0.002470	0.002580	550770

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.044484	0.042592	0.999957

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.891709	0.050797	-1.99127	-1.79215	550770	-1.930955	-1.854080

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-37.24	<.0001

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

PARAMSORT=1 Parameter Code=C64849B Label=Treatment contrast, IDegLira - IDeg Statement Number=2

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.000386	0.007414	0.007801	406826

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.052138	0.049559	0.999950

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.883314	0.088322	-1.05642	-0.71021	406826	-0.940071	-0.823341

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-10.00	<.0001

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

PARAMSORT=2 Parameter Code=HBA1CONV Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.037201	0.590373	0.627611	283778

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.063075	0.059339	0.999941

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-11.021753	0.792219	-12.5745	-9.46903	283778	-11.570104	-10.432458

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-13.91	<.0001

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

PARAMSORT=2 Parameter Code=HBA1CONV Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.013115	0.295126	0.308254	550770

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.044484	0.042592	0.999957

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-20.676379	0.555206	-21.7646	-19.5882	550770	-21.105334	-20.265098

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-37.24	<.0001

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

PARAMSORT=2 Parameter Code=HBA1CONV Label=Treatment contrast, IDegLira - IDeg Statement Number=2

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.046134	0.885743	0.931923	406826

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.052138	0.049559	0.999950

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-9.654626	0.965362	-11.5467	-7.76255	406826	-10.274981	-8.999121

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-10.00	<.0001

7: 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 453
 Number of Observations Used 453
 Number of Events 106
 Number of Trials 453

Class Level Information

Class	Levels	Values
TRTPN	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	106
2	N	347

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

Parameter Information

Parameter	Effect	TRTPN	PREAD
Prm1	Intercept		
Prm2	TRTPN	1	
Prm3	TRTPN	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HBA1CBL		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-218.6220	
Full Log Likelihood		-218.6220	
AIC (smaller is better)		445.2439	
AICC (smaller is better)		445.3332	
BIC (smaller is better)		461.7075	

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	
Intercept		0.5081	1.0333	-1.5171	2.5332
TRTPN 1	1	1.9218	0.3530	1.2299	2.6138
TRTPN 2	0	0.0000	0.0000	0.0000	0.0000

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	
PREAD	BASAL INSULIN + METFORMIN	1	0.3170	0.2359	-0.1454	0.7795
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HBA1CBL		1	-0.3789	0.1138	-0.6019	-0.1559
Scale		0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Wald Chi-Square	Pr > ChiSq
Intercept		0.24	0.6229
TRTPN	1	29.63	<.0001
TRTPN	2		
PREAD	BASAL INSULIN + METFORMIN	1.81	0.1791
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HBA1CBL		11.09	0.0009
Scale			

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	-0.7999	0.1284	-6.23	<.0001	0.05
TRTPN	LSMeans frequency, IDeg	-2.7218	0.3318	-8.20	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	LSMeans frequency, IDegLira	-1.0517	-0.5482	0.4494	0.3494	0.5780
TRTPN	LSMeans frequency, IDeg	-3.3721	-2.0715	0.06576	0.03432	0.1260

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
TRTPN	Treatment odds ratio, IDegLira / IDeg	1.9218	0.3530	5.44	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
TRTPN	Treatment odds ratio, IDegLira / IDeg	1.2299	2.6138	6.8335

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
TRTPN	Treatment odds ratio, IDegLira / IDeg	3.4209	13.6505

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 453
 Number of Observations Used 453
 Number of Events 177
 Number of Trials 453

Class Level Information

Class	Levels	Values
TRTPN	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	177
2	N	276

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

Parameter Information

Parameter	Effect	TRTPN	PREAD
Prm1	Intercept		
Prm2	TRTPN	1	
Prm3	TRTPN	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HBALCBL		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-260.6635	
Full Log Likelihood		-260.6635	
AIC (smaller is better)		529.3269	
AICC (smaller is better)		529.4162	
BIC (smaller is better)		545.7905	

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	
Intercept		2.0446	0.8816	0.3168	3.7724
TRTPN 1	1	1.8428	0.2613	1.3307	2.3550
TRTPN 2	0	0.0000	0.0000	0.0000	0.0000

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	
PREAD	BASAL INSULIN + METFORMIN	1	0.3773	0.2128	-0.0397	0.7944
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HBA1CBL		1	-0.4514	0.0989	-0.6452	-0.2576
Scale		0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Wald Chi-Square	Pr > ChiSq
Intercept		5.38	0.0204
TRTPN	1	49.74	<.0001
TRTPN	2		
PREAD	BASAL INSULIN + METFORMIN	3.14	0.0762
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HBA1CBL		20.83	<.0001
Scale			

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	0.03918	0.1197	0.33	0.7433	0.05
TRTPN	LSMeans frequency, IDeg	-1.8037	0.2329	-7.75	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	LSMeans frequency, IDegLira	-0.1954	0.2737	1.0400	0.8225	1.3149
TRTPN	LSMeans frequency, IDeg	-2.2601	-1.3473	0.1647	0.1043	0.2600

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
TRTPN	Treatment odds ratio, IDegLira / IDeg	1.8428	0.2613	7.05	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
TRTPN	Treatment odds ratio, IDegLira / IDeg	1.3307	2.3550	6.3145

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
TRTPN	Treatment odds ratio, IDegLira / IDeg	3.7837	10.5380

8: 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	453
Number of Observations Used	453
Number of Events	102
Number of Trials	453

Class Level Information

Class	Levels	Values
trtpn	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	102
2	N	351

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

Parameter Information

Parameter	Effect	trtpn	PREAD
Prm1	Intercept		
Prm2	trtpn	1	
Prm3	trtpn	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HBALCBL		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-213.6936	
Full Log Likelihood		-213.6936	
AIC (smaller is better)		435.3871	
AICC (smaller is better)		435.4764	
BIC (smaller is better)		451.8507	

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	
Intercept	1	0.2883	1.0497	-1.7691	2.3457
trtpn	1	1.9903	0.3689	1.2673	2.7132

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	
trtpn 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.3750	0.2392	-0.0939	0.8439
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HbA1cBL	1	-0.3703	0.1152	-0.5960	-0.1446
Scale	0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	0.08	0.7836
trtpn 1	29.11	<.0001
trtpn 2		
PREAD BASAL INSULIN + METFORMIN	2.46	0.1170
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HbA1cBL	10.34	0.0013
Scale		

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	-0.8458	0.1296	-6.53	<.0001	0.05
trtpn	LSMeans frequency, IDeg	-2.8361	0.3483	-8.14	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans frequency, IDegLira	-1.0998	-0.5918	0.4292	0.3329	0.5533
trtpn	LSMeans frequency, IDeg	-3.5188	-2.1534	0.05866	0.02964	0.1161

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
trtpn	Treatment odds ratio, IDegLira / IDeg	1.9903	0.3689	5.40	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
trtpn	Treatment odds ratio, IDegLira / IDeg	1.2673	2.7132	7.3176

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment odds ratio, IDegLira / IDeg	3.5513	15.0781

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 453
 Number of Observations Used 453
 Number of Events 170
 Number of Trials 453

Class Level Information

Class	Levels	Values
trtpn	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	170
2	N	283

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

Parameter Information

Parameter	Effect	trtpn	PREAD
Prm1	Intercept		
Prm2	trtpn	1	
Prm3	trtpn	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HBA1CBL		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-260.9980	
Full Log Likelihood		-260.9980	
AIC (smaller is better)		529.9960	
AICC (smaller is better)		530.0853	
BIC (smaller is better)		546.4596	

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits
Intercept	1	1.5955	0.8770	-0.1235 3.3144
trtpn 1	1	1.8007	0.2638	1.2836 2.3179

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	
trtpn 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.3871	0.2125	-0.0293	0.8035
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HbA1cBL	1	-0.4061	0.0979	-0.5980	-0.2142
Scale	0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	3.31	0.0689
trtpn 1	46.58	<.0001
trtpn 2		
PREAD BASAL INSULIN + METFORMIN	3.32	0.0685
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HbA1cBL	17.21	<.0001
Scale		

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	-0.04197	0.1190	-0.35	0.7243	0.05
trtpn	LSMeans frequency, IDeg	-1.8427	0.2361	-7.80	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans frequency, IDegLira	-0.2752	0.1913	0.9589	0.7594	1.2108
trtpn	LSMeans frequency, IDeg	-2.3055	-1.3799	0.1584	0.09971	0.2516

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
trtpn	Treatment odds ratio, IDegLira / IDeg	1.8007	0.2638	6.82	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
trtpn	Treatment odds ratio, IDegLira / IDeg	1.2836	2.3179	6.0541

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment odds ratio, IDegLira / IDeg	3.6096	10.1540

9: 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	453
Number of Observations Used	453
Number of Events	62
Number of Trials	453

Class Level Information

Class	Levels	Values
trtpn	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	62
2	N	391

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

Parameter Information

Parameter	Effect	trtpn	PREAD
Prm1	Intercept		
Prm2	trtpn	1	
Prm3	trtpn	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HbA1cCBL		
Prm7	WGtbl		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-159.3887	
Full Log Likelihood		-159.3887	
AIC (smaller is better)		328.7775	
AICC (smaller is better)		328.9117	
BIC (smaller is better)		349.3569	

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	
Intercept	1	-1.3809	1.5664	-4.4511	1.6892
trtpn 1	1	2.4694	0.6029	1.2877	3.6512
trtpn 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.0531	0.2874	-0.5103	0.6165
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HBA1CBL	1	-0.3826	0.1438	-0.6645	-0.1007
WGTL	1	0.0107	0.0108	-0.0104	0.0318
Scale	0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	0.78	0.3780
trtpn 1	16.77	<.0001
trtpn 2		
PREAD BASAL INSULIN + METFORMIN	0.03	0.8535
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HBA1CBL	7.08	0.0078
WGTL	0.99	0.3188
Scale		

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	-1.4921	0.1553	-9.61	<.0001	0.05
trtpn	LSMeans frequency, IDeg	-3.9615	0.5867	-6.75	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans frequency, IDegLira	-1.7965	-1.1877	0.2249	0.1659	0.3049
trtpn	LSMeans frequency, IDeg	-5.1113	-2.8117	0.01903	0.006028	0.06010

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
trtpn	Treatment odds ratio, IDegLira / IDeg	2.4694	0.6029	4.10	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
trtpn	Treatment odds ratio, IDegLira / IDeg	1.2877	3.6512	11.8157

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

Parameter Code=HB65WOWG

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment odds ratio, IDegLira / IDeg	3.6243	38.5206

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	453
Number of Observations Used	453
Number of Events	105
Number of Trials	453

Class Level Information

Class	Levels	Values
trtpn	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	105
2	N	348

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

Parameter Information

Parameter	Effect	trtpn	PREAD
Prm1	Intercept		
Prm2	trtpn	1	
Prm3	trtpn	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HBALCBL		
Prm7	WGTLBL		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-211.2368	
Full Log Likelihood		-211.2368	
AIC (smaller is better)		432.4737	
AICC (smaller is better)		432.6079	
BIC (smaller is better)		453.0531	

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	
Intercept	1	0.5368	1.2695	-1.9514	3.0251
trtpn 1	1	2.3385	0.4097	1.5354	3.1416
trtpn 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.2414	0.2407	-0.2304	0.7132
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HBA1CBL	1	-0.4075	0.1165	-0.6359	-0.1791
WGTBL	1	-0.0017	0.0094	-0.0200	0.0167
Scale	0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	0.18	0.6724
trtpn 1	32.57	<.0001
trtpn 2		
PREAD BASAL INSULIN + METFORMIN	1.01	0.3160
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HBA1CBL	12.23	0.0005
WGTBL	0.03	0.8596
Scale		

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	-0.7744	0.1286	-6.02	<.0001	0.05
trtpn	LSMeans frequency, IDeg	-3.1129	0.3918	-7.95	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans frequency, IDegLira	-1.0264	-0.5224	0.4610	0.3583	0.5931
trtpn	LSMeans frequency, IDeg	-3.8807	-2.3450	0.04447	0.02064	0.09584

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
trtpn	Treatment odds ratio, IDegLira / IDeg	2.3385	0.4097	5.71	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
trtpn	Treatment odds ratio, IDegLira / IDeg	1.5354	3.1416	10.3655

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

Parameter Code=HBA7WOWG

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment odds ratio, IDegLira / IDeg	4.6432	23.1402

10: 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	453
Number of Observations Used	453
Number of Events	61
Number of Trials	453

Class Level Information

Class	Levels	Values
trtpn	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	61
2	N	392

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

Parameter Information

Parameter	Effect	trtpn	PREAD
Prm1	Intercept		
Prm2	trtpn	1	
Prm3	trtpn	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HBA1CBL		
Prm7	WGTBL		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-157.5765	
Full Log Likelihood		-157.5765	
AIC (smaller is better)		325.1529	
AICC (smaller is better)		325.2871	
BIC (smaller is better)		345.7324	

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	
Intercept	1	-1.2594	1.5841	-4.3643	1.8454
trtpn 1	1	2.4496	0.6033	1.2671	3.6321
trtpn 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.0944	0.2894	-0.4728	0.6615
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HBA1CBL	1	-0.4041	0.1466	-0.6915	-0.1167
WGTBL	1	0.0113	0.0108	-0.0099	0.0325
Scale	0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	0.63	0.4266
trtpn 1	16.48	<.0001
trtpn 2		
PREAD BASAL INSULIN + METFORMIN	0.11	0.7443
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HBA1CBL	7.59	0.0059
WGTBL	1.09	0.2975
Scale		

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	-1.5204	0.1574	-9.66	<.0001	0.05
trtpn	LSMeans frequency, IDeg	-3.9700	0.5871	-6.76	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans frequency, IDegLira	-1.8288	-1.2120	0.2186	0.1606	0.2976
trtpn	LSMeans frequency, IDeg	-5.1208	-2.8192	0.01887	0.005972	0.05965

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
trtpn	Treatment odds ratio, IDegLira / IDeg	2.4496	0.6033	4.06	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
trtpn	Treatment odds ratio, IDegLira / IDeg	1.2671	3.6321	11.5836

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

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment odds ratio, IDegLira / IDeg	3.5504	37.7934

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	453
Number of Observations Used	453
Number of Events	101
Number of Trials	453

Class Level Information

Class	Levels	Values
trtpn	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Response Profile

Ordered Value	AVALC	Total Frequency
1	Y	101
2	N	352

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

Parameter Information

Parameter	Effect	trtpn	PREAD
Prm1	Intercept		
Prm2	trtpn	1	
Prm3	trtpn	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD
Prm6	HB1CBL		
Prm7	WG1BL		

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Log Likelihood		-209.2402	
Full Log Likelihood		-209.2402	
AIC (smaller is better)		428.4804	
AICC (smaller is better)		428.6146	
BIC (smaller is better)		449.0598	

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	
Intercept	1	0.1064	1.2722	-2.3869	2.5998
trtpn 1	1	2.2639	0.4097	1.4609	3.0669
trtpn 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.2414	0.2424	-0.2338	0.7166
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
HBA1CBL	1	-0.3788	0.1165	-0.6072	-0.1505
WGTBL	1	0.0008	0.0094	-0.0176	0.0193
Scale	0	1.0000	0.0000	1.0000	1.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	0.01	0.9333
trtpn 1	30.53	<.0001
trtpn 2		
PREAD BASAL INSULIN + METFORMIN	0.99	0.3194
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
HBA1CBL	10.57	0.0011
WGTBL	0.01	0.9292
Scale		

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	-0.8334	0.1295	-6.44	<.0001	0.05
trtpn	LSMeans frequency, IDeg	-3.0973	0.3912	-7.92	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans frequency, IDegLira	-1.0873	-0.5796	0.4346	0.3371	0.5601
trtpn	LSMeans frequency, IDeg	-3.8640	-2.3306	0.04517	0.02098	0.09724

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha
trtpn	Treatment odds ratio, IDegLira / IDeg	2.2639	0.4097	5.53	<.0001	0.05

Least Squares Means Estimate

Effect	Label	Lower	Upper	Exponentiated
trtpn	Treatment odds ratio, IDegLira / IDeg	1.4609	3.0669	9.6205

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

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment odds ratio, IDegLira / IDeg	4.3097	21.4759

**11: Body weight after 26 weeks of treatment – change from baseline – confirmatory statistical analysis
 – full analysis set - appendix**

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	8.0164

Fit Statistics

-2 Res Log Likelihood 2235.4
 AIC (Smaller is Better) 2237.4
 AICC (Smaller is Better) 2237.4
 BIC (Smaller is Better) 2241.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-1.4889	0.8516	449	-1.75
trtpn		1	-1.0762	0.2835	449	-3.80
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3488	0.2675	449	1.30
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			1.0227	0.01074	449	95.25

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0811	0.05
trtpn		1	0.0002	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1930	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-3.1625	0.1847
trtpn		1	-1.6334	-0.5189
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1770	0.8746
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			1.0016	1.0438

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	14.40	0.0002
PREAD	1	449	1.70	0.1930
BASE	1	449	9072.25	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	75.3159	0.1632	449	461.54	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	76.3920	0.2311	449	330.49	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	74.9952	75.6366	5.12E32	3.715E32	7.056E32
trtpn	LSMeans, IDeg	75.9378	76.8463	1.502E33	9.536E32	2.366E33

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-1.0762	0.2835	449	-3.80

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
- full analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0002	0.05	-1.6334	-0.5189	0.3409

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.1953	0.5952

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	38.9624

Fit Statistics

-2 Res Log Likelihood	2946.9
AIC (Smaller is Better)	2948.9
AICC (Smaller is Better)	2948.9
BIC (Smaller is Better)	2953.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-3.2825	1.8774	449	-1.75
trtpn		1	-2.3725	0.6251	449	-3.80
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.7689	0.5898	449	1.30
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			1.0227	0.01074	449	95.25

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0811	0.05
trtpn		1	0.0002	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1930	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-6.9722	0.4072
trtpn		1	-3.6010	-1.1440
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.3902	1.9281
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			1.0016	1.0438

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	14.40	0.0002
PREAD	1	449	1.70	0.1930
BASE	1	449	9072.25	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	166.04	0.3598	449	461.54	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	168.42	0.5096	449	330.49	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	165.34	166.75	1.293E72	6.376E71	2.622E72
trtpn	LSMeans, IDeg	167.41	169.42	1.387E73	5.094E72	3.775E73

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-2.3725	0.6251	449	-3.80

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
- full analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0002	0.05	-3.6010	-1.1440	0.09325

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.02730	0.3185

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	8.0164

Fit Statistics

-2 Res Log Likelihood 2235.4
 AIC (Smaller is Better) 2237.4
 AICC (Smaller is Better) 2237.4
 BIC (Smaller is Better) 2241.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-1.4889	0.8516	449	-1.75
trtpn		1	-1.0762	0.2835	449	-3.80
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3488	0.2675	449	1.30
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.02267	0.01074	449	2.11

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0811	0.05
trtpn		1	0.0002	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1930	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0353	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-3.1625	0.1847
trtpn		1	-1.6334	-0.5189
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1770	0.8746
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.001572	0.04377

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	14.40	0.0002
PREAD	1	449	1.70	0.1930
BASE	1	449	4.46	0.0353

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-0.6766	0.1632	449	-4.15	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.3996	0.2311	449	1.73	0.0846

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-0.9973	-0.3559
trtpn	Change from baseline, IDeg	0.05	-0.05471	0.8538

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	38.9624

Fit Statistics

-2 Res Log Likelihood	2946.9
AIC (Smaller is Better)	2948.9
AICC (Smaller is Better)	2948.9
BIC (Smaller is Better)	2953.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-3.2825	1.8774	449	-1.75
trtpn		1	-2.3725	0.6251	449	-3.80
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.7689	0.5898	449	1.30
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.02267	0.01074	449	2.11

Body weight after 26 weeks of treatment - change from baseline - confirmatory statistical analysis
 - full analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0811	0.05
trtpn		1	0.0002	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1930	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0353	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-6.9722	0.4072
trtpn		1	-3.6010	-1.1440
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.3902	1.9281
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.001572	0.04377

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	14.40	0.0002
PREAD	1	449	1.70	0.1930
BASE	1	449	4.46	0.0353

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-1.4916	0.3598	449	-4.15	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.8809	0.5096	449	1.73	0.0846

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-2.1987	-0.7846
trtpn	Change from baseline, IDeg	0.05	-0.1206	1.8823

**12: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis –
 PP analysis set - appendix**

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	8.3053

Fit Statistics

-2 Res Log Likelihood	2142.1
AIC (Smaller is Better)	2144.1
AICC (Smaller is Better)	2144.1
BIC (Smaller is Better)	2148.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-1.5403	0.8925	427	-1.73
trtan		1	-1.0802	0.2968	427	-3.64
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3398	0.2793	427	1.22
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			1.0236	0.01127	427	90.86

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - PP analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0851	0.05
trtan		1	0.0003	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.2244	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			-3.2945	0.2140
trtan		1	-1.6637	-0.4967
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-0.2092	0.8887
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			1.0014	1.0457

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	13.24	0.0003
PREAD	1	427	1.48	0.2244
BASE	1	427	8254.99	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtan	LSMeans, IDegLira	WORK.ADATA2	75.2965	0.1698	427	443.42	<.0001	0.05
trtan	LSMeans, IDeg	WORK.ADATA2	76.3767	0.2427	427	314.74	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtan	LSMeans, IDegLira	74.9628	75.6303	5.022E32	3.597E32	7.012E32
trtan	LSMeans, IDeg	75.8998	76.8537	1.479E33	9.18E32	2.383E33

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtan	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-1.0802	0.2968	427	-3.64

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
PP analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtan	Treatment contrast, IDegLira - IDeg	0.0003	0.05	-1.6637	-0.4967	0.3395

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtan	Treatment contrast, IDegLira - IDeg	0.1894	0.6085

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
 PP analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	40.3667

Fit Statistics

-2 Res Log Likelihood	2818.8
AIC (Smaller is Better)	2820.8
AICC (Smaller is Better)	2820.8
BIC (Smaller is Better)	2824.8

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-3.3957	1.9676	427	-1.73
trtan		1	-2.3814	0.6544	427	-3.64
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.7491	0.6157	427	1.22
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			1.0236	0.01127	427	90.86

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - PP analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0851	0.05
trtan		1	0.0003	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.2244	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			-7.2631	0.4717
trtan		1	-3.6677	-1.0951
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4611	1.9593
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			1.0014	1.0457

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	13.24	0.0003
PREAD	1	427	1.48	0.2244
BASE	1	427	8254.99	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtan	LSMeans, IDegLira	WORK.ADATA2	166.00	0.3744	427	443.42	<.0001	0.05
trtan	LSMeans, IDeg	WORK.ADATA2	168.38	0.5350	427	314.74	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtan	LSMeans, IDegLira	165.26	166.74	1.239E72	5.936E71	2.586E72
trtan	LSMeans, IDeg	167.33	169.43	1.341E73	4.684E72	3.837E73

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtan	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-2.3814	0.6544	427	-3.64

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
PP analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtan	Treatment contrast, IDegLira - IDeg	0.0003	0.05	-3.6677	-1.0951	0.09242

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtan	Treatment contrast, IDegLira - IDeg	0.02553	0.3345

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
 PP analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	8.3053

Fit Statistics

-2 Res Log Likelihood	2142.1
AIC (Smaller is Better)	2144.1
AICC (Smaller is Better)	2144.1
BIC (Smaller is Better)	2148.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-1.5403	0.8925	427	-1.73
trtan		1	-1.0802	0.2968	427	-3.64
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3398	0.2793	427	1.22
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.02356	0.01127	427	2.09

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - PP analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0851	0.05
trtan		1	0.0003	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.2244	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0371	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			-3.2945	0.2140
trtan		1	-1.6637	-0.4967
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-0.2092	0.8887
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.001415	0.04570

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	13.24	0.0003
PREAD	1	427	1.48	0.2244
BASE	1	427	4.37	0.0371

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtan	Change from baseline, IDegLira	WORK.ADATA2	-0.6700	0.1698	427	-3.95	<.0001
trtan	Change from baseline, IDeg	WORK.ADATA2	0.4102	0.2427	427	1.69	0.0917

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtan	Change from baseline, IDegLira	0.05	-1.0038	-0.3363
trtan	Change from baseline, IDeg	0.05	-0.06682	0.8871

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
 PP analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	431

Number of Observations

Number of Observations Read	431
Number of Observations Used	431
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	40.3667

Fit Statistics

-2 Res Log Likelihood	2818.8
AIC (Smaller is Better)	2820.8
AICC (Smaller is Better)	2820.8
BIC (Smaller is Better)	2824.8

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-3.3957	1.9676	427	-1.73
trtan		1	-2.3814	0.6544	427	-3.64
trtan		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.7491	0.6157	427	1.22
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.02356	0.01127	427	2.09

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - PP analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0851	0.05
trtan		1	0.0003	0.05
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		0.2244	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0371	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Actual Treatment for Period 01 (N)	Lower	Upper
Intercept			-7.2631	0.4717
trtan		1	-3.6677	-1.0951
trtan		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4611	1.9593
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.001415	0.04570

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtan	1	427	13.24	0.0003
PREAD	1	427	1.48	0.2244
BASE	1	427	4.37	0.0371

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtan	Change from baseline, IDegLira	WORK.ADATA2	-1.4772	0.3744	427	-3.95	<.0001
trtan	Change from baseline, IDeg	WORK.ADATA2	0.9042	0.5350	427	1.69	0.0917

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtan	Change from baseline, IDegLira	0.05	-2.2130	-0.7414
trtan	Change from baseline, IDeg	0.05	-0.1473	1.9558

**13: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis –
 completer analysis set - appendix**

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	429

Number of Observations

Number of Observations Read	429
Number of Observations Used	429
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	8.3003

Fit Statistics

-2 Res Log Likelihood	2131.9
AIC (Smaller is Better)	2133.9
AICC (Smaller is Better)	2133.9
BIC (Smaller is Better)	2137.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-1.3952	0.8950	425	-1.56
trtpn		1	-1.1604	0.2986	425	-3.89
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3621	0.2799	425	1.29
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			1.0225	0.01126	425	90.79

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.1198	0.05
trtpn		1	0.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1964	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-3.1543	0.3639
trtpn		1	-1.7473	-0.5735
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1880	0.9123
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			1.0003	1.0446

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	15.10	0.0001
PREAD	1	425	1.67	0.1964
BASE	1	425	8243.01	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	75.3056	0.1694	425	444.45	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	76.4660	0.2451	425	311.93	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	74.9726	75.6386	5.068E32	3.632E32	7.07E32
trtpn	LSMeans, IDeg	75.9842	76.9478	1.617E33	9.989E32	2.618E33

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-1.1604	0.2986	425	-3.89

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
completer analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0001	0.05	-1.7473	-0.5735	0.3134

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.1742	0.5635

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
 completer analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	429

Number of Observations

Number of Observations Read	429
Number of Observations Used	429
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	40.3426

Fit Statistics

-2 Res Log Likelihood	2805.4
AIC (Smaller is Better)	2807.4
AICC (Smaller is Better)	2807.5
BIC (Smaller is Better)	2811.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-3.0759	1.9731	425	-1.56
trtpn		1	-2.5583	0.6583	425	-3.89
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.7984	0.6171	425	1.29
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			1.0225	0.01126	425	90.79

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.1198	0.05
trtpn		1	0.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1964	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-6.9541	0.8023
trtpn		1	-3.8522	-1.2644
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4145	2.0113
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			1.0003	1.0446

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	15.10	0.0001
PREAD	1	425	1.67	0.1964
BASE	1	425	8243.01	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	166.02	0.3735	425	444.45	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	168.58	0.5404	425	311.93	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	165.29	166.75	1.264E72	6.066E71	2.634E72
trtpn	LSMeans, IDeg	167.52	169.64	1.632E73	5.642E72	4.722E73

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-2.5583	0.6583	425	-3.89

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
completer analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0001	0.05	-3.8522	-1.2644	0.07744

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.02123	0.2824

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
 completer analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	429

Number of Observations

Number of Observations Read	429
Number of Observations Used	429
Number of Observations Not Used	0

Covariance Parameter
 Estimates

Cov Parm	Estimate
Residual	8.3003

Fit Statistics

-2 Res Log Likelihood	2131.9
AIC (Smaller is Better)	2133.9
AICC (Smaller is Better)	2133.9
BIC (Smaller is Better)	2137.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-1.3952	0.8950	425	-1.56
trtpn		1	-1.1604	0.2986	425	-3.89
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3621	0.2799	425	1.29
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.02247	0.01126	425	2.00

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set - appendix

Parameter Code=C25208X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.1198	0.05
trtpn		1	0.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1964	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0466	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-3.1543	0.3639
trtpn		1	-1.7473	-0.5735
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1880	0.9123
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.000336	0.04461

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	15.10	0.0001
PREAD	1	425	1.67	0.1964
BASE	1	425	3.98	0.0466

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-0.6760	0.1694	425	-3.99	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.4844	0.2451	425	1.98	0.0488

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-1.0090	-0.3429
trtpn	Change from baseline, IDeg	0.05	0.002600	0.9663

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	429

Number of Observations

Number of Observations Read	429
Number of Observations Used	429
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	40.3426

Fit Statistics

-2 Res Log Likelihood	2805.4
AIC (Smaller is Better)	2807.4
AICC (Smaller is Better)	2807.5
BIC (Smaller is Better)	2811.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-3.0759	1.9731	425	-1.56
trtpn		1	-2.5583	0.6583	425	-3.89
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.7984	0.6171	425	1.29
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.02247	0.01126	425	2.00

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - completer analysis set - appendix

Parameter Code=WEIGHTU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.1198	0.05
trtpn		1	0.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1964	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0466	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-6.9541	0.8023
trtpn		1	-3.8522	-1.2644
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4145	2.0113
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.000336	0.04461

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	425	15.10	0.0001
PREAD	1	425	1.67	0.1964
BASE	1	425	3.98	0.0466

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-1.4903	0.3735	425	-3.99	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	1.0680	0.5404	425	1.98	0.0488

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-2.2245	-0.7561
trtpn	Change from baseline, IDeg	0.05	0.005731	2.1302

14: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – MMRM – full analysis set - appendix

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	2	1 2
avisitn	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

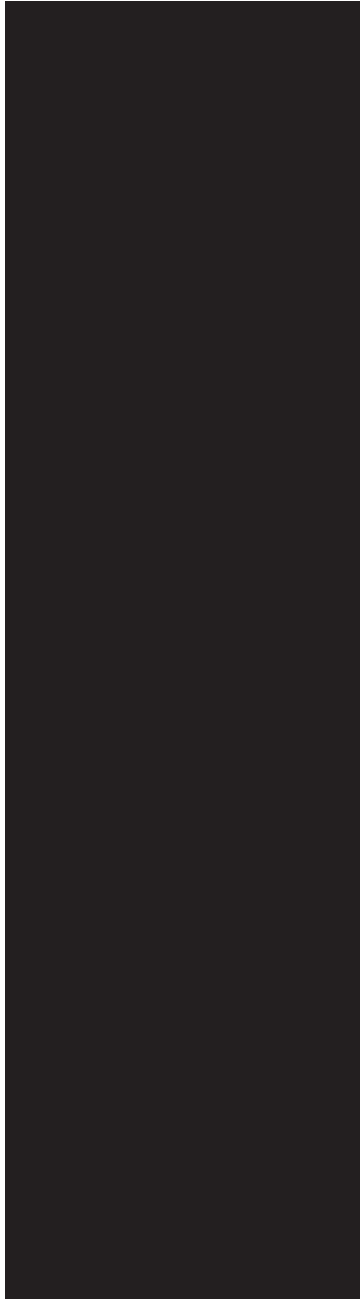
Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	453	



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2597
Number of Observations Not Used	121

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set - appendix

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	11799.74282062	
1	2	8867.20333115	0.00000625
2	1	8867.19027918	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	2.0140
UN(2,1)	SUBJID	1.9791
UN(2,2)	SUBJID	3.9752
UN(3,1)	SUBJID	2.1981
UN(3,2)	SUBJID	3.6319
UN(3,3)	SUBJID	5.2127
UN(4,1)	SUBJID	2.1194
UN(4,2)	SUBJID	3.6227
UN(4,3)	SUBJID	4.9685
UN(4,4)	SUBJID	6.0757
UN(5,1)	SUBJID	2.1682
UN(5,2)	SUBJID	3.7181
UN(5,3)	SUBJID	5.0852
UN(5,4)	SUBJID	5.7532
UN(5,5)	SUBJID	6.9717
UN(6,1)	SUBJID	2.3366
UN(6,2)	SUBJID	3.7858
UN(6,3)	SUBJID	5.2013
UN(6,4)	SUBJID	5.7740
UN(6,5)	SUBJID	6.5474
UN(6,6)	SUBJID	8.3028

Fit Statistics

-2 Res Log Likelihood	8867.2
AIC (Smaller is Better)	8909.2
AICC (Smaller is Better)	8909.6
BIC (Smaller is Better)	8995.6

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	2932.55	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN(avisitn)	6	436	2.83	0.0103
PREAD(avisitn)	6	433	1.45	0.1950
BASE(avisitn)	6	433	5778.27	<.0001

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

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	75.2925	0.1691	431.5	445.17	<.0001
TRT01PN(avisitn)	LSMeans, IDeg	WORK.ANA_DATA	76.4274	0.2411	440.4	316.99	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
TRT01PN(avisitn)	LSMeans, IDegLira	0.05	74.9601	75.6249
TRT01PN(avisitn)	LSMeans, IDeg	0.05	75.9536	76.9013

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

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	2	1 2
avisitn	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	453	



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2597
Number of Observations Not Used	121

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	15877.43246205	
1	2	12944.89297256	0.00000315
2	1	12944.87992061	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	9.7886
UN(2,1)	SUBJID	9.6190
UN(2,2)	SUBJID	19.3211
UN(3,1)	SUBJID	10.6836
UN(3,2)	SUBJID	17.6521
UN(3,3)	SUBJID	25.3355
UN(4,1)	SUBJID	10.3012
UN(4,2)	SUBJID	17.6076
UN(4,3)	SUBJID	24.1485
UN(4,4)	SUBJID	29.5302
UN(5,1)	SUBJID	10.5383
UN(5,2)	SUBJID	18.0715
UN(5,3)	SUBJID	24.7161
UN(5,4)	SUBJID	27.9627
UN(5,5)	SUBJID	33.8849
UN(6,1)	SUBJID	11.3569
UN(6,2)	SUBJID	18.4005
UN(6,3)	SUBJID	25.2801
UN(6,4)	SUBJID	28.0636
UN(6,5)	SUBJID	31.8228
UN(6,6)	SUBJID	40.3546

Fit Statistics

-2 Res Log Likelihood	12944.9
AIC (Smaller is Better)	12986.9
AICC (Smaller is Better)	12987.2
BIC (Smaller is Better)	13073.3

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	2932.55	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN(avisitn)	6	436	2.83	0.0103
PREAD(avisitn)	6	433	1.45	0.1950
BASE(avisitn)	6	433	5778.27	<.0001

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

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	165.99	0.3729	431.5	445.17	<.0001
TRT01PN(avisitn)	LSMeans, IDeg	WORK.ANA_DATA	168.49	0.5315	440.4	316.99	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
TRT01PN(avisitn)	LSMeans, IDegLira	0.05	165.26	166.72
TRT01PN(avisitn)	LSMeans, IDeg	0.05	167.45	169.54

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

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	2	1 2
avisitn	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

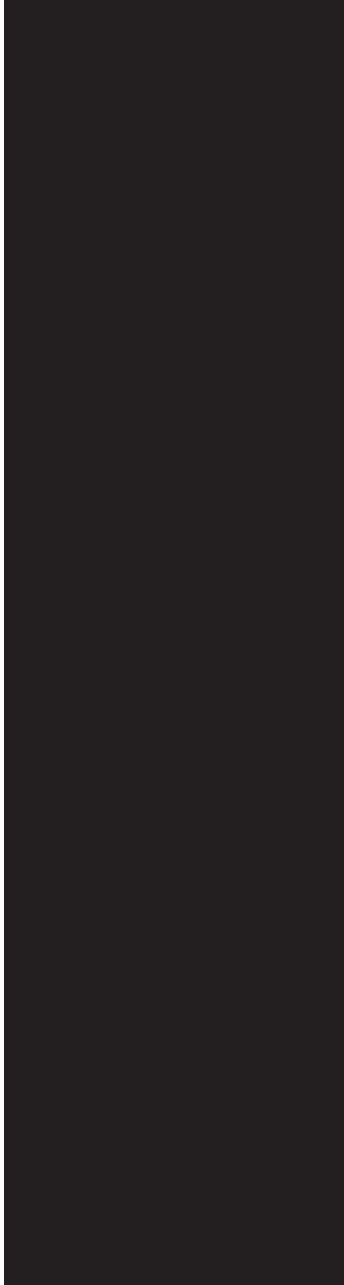
Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Class Level Information

Class	Levels	Values
SUBJID	453	



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2597
Number of Observations Not Used	121

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set - appendix

Short Topic Code=C25208X Long label=Body weight (kg)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	11799.74282062	
1	2	8867.20333114	0.00000625
2	1	8867.19027918	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	2.0140
UN(2,1)	SUBJID	1.9791
UN(2,2)	SUBJID	3.9752
UN(3,1)	SUBJID	2.1981
UN(3,2)	SUBJID	3.6319
UN(3,3)	SUBJID	5.2127
UN(4,1)	SUBJID	2.1194
UN(4,2)	SUBJID	3.6227
UN(4,3)	SUBJID	4.9685
UN(4,4)	SUBJID	6.0757
UN(5,1)	SUBJID	2.1682
UN(5,2)	SUBJID	3.7181
UN(5,3)	SUBJID	5.0852
UN(5,4)	SUBJID	5.7532
UN(5,5)	SUBJID	6.9717
UN(6,1)	SUBJID	2.3366
UN(6,2)	SUBJID	3.7858
UN(6,3)	SUBJID	5.2013
UN(6,4)	SUBJID	5.7740
UN(6,5)	SUBJID	6.5474
UN(6,6)	SUBJID	8.3028

Fit Statistics

-2 Res Log Likelihood	8867.2
AIC (Smaller is Better)	8909.2
AICC (Smaller is Better)	8909.6
BIC (Smaller is Better)	8995.6

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	2932.55	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN(avisitn)	6	436	2.83	0.0103
PREAD(avisitn)	6	433	1.45	0.1950
BASE(avisitn)	6	433	2.12	0.0498

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set - appendix

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	-0.6806	0.1691	431.5	-4.02
TRT01PN(avisitn)	Change from baseline, IDeg	WORK.ANA_DATA	0.4543	0.2411	440.4	1.88

Least Squares Means Estimates

Effect	Label	Pr > t	Alpha	Lower	Upper
TRT01PN(avisitn)	Change from baseline, IDegLira	<.0001	0.05	-1.0131	-0.3482
TRT01PN(avisitn)	Change from baseline, IDeg	0.0602	0.05	-0.01953	0.9282

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF
TRT01PN(avisitn)	Treatment contrast, IDegLira - IDeg	WORK.ANA_DATA	-1.1350	0.2951	437.4

Least Squares Means Estimate

Effect	Label	t Value	Pr > t	Alpha	Lower	Upper
TRT01PN(avisitn)	Treatment contrast, IDegLira - IDeg	-3.85	0.0001	0.05	-1.7150	-0.5549

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

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	2	1 2
avisitn	6	100 150 190 230 270 330
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Class Level Information

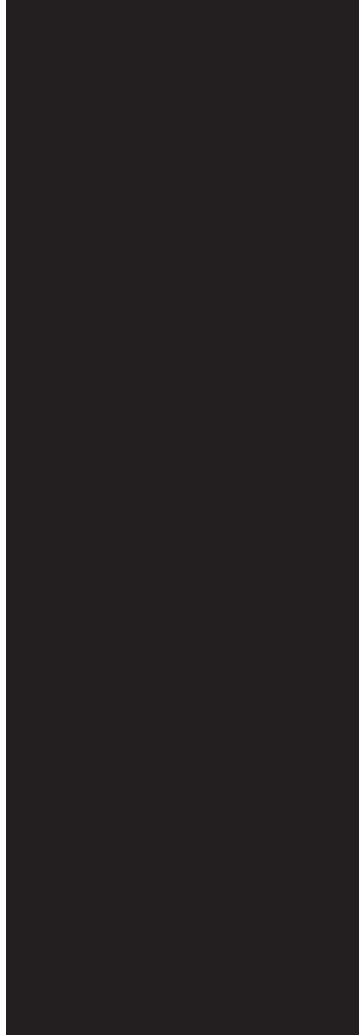
Class	Levels	Values
SUBJID	453	



Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis -
MMRM - full analysis set - appendix

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure



Dimensions

Covariance Parameters	21
Columns in X	31
Columns in Z	0
Subjects	453
Max Obs per Subject	6

Number of Observations

Number of Observations Read	2718
Number of Observations Used	2597
Number of Observations Not Used	121

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set - appendix

Short Topic Code=WEIGHTU Long label=Body weight (lb)

The Mixed Procedure

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	15877.43246205	
1	2	12944.89297256	0.00000315
2	1	12944.87992060	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate
UN(1,1)	SUBJID	9.7886
UN(2,1)	SUBJID	9.6190
UN(2,2)	SUBJID	19.3211
UN(3,1)	SUBJID	10.6836
UN(3,2)	SUBJID	17.6521
UN(3,3)	SUBJID	25.3355
UN(4,1)	SUBJID	10.3012
UN(4,2)	SUBJID	17.6076
UN(4,3)	SUBJID	24.1485
UN(4,4)	SUBJID	29.5302
UN(5,1)	SUBJID	10.5383
UN(5,2)	SUBJID	18.0715
UN(5,3)	SUBJID	24.7161
UN(5,4)	SUBJID	27.9627
UN(5,5)	SUBJID	33.8849
UN(6,1)	SUBJID	11.3569
UN(6,2)	SUBJID	18.4005
UN(6,3)	SUBJID	25.2801
UN(6,4)	SUBJID	28.0636
UN(6,5)	SUBJID	31.8228
UN(6,6)	SUBJID	40.3546

Fit Statistics

-2 Res Log Likelihood	12944.9
AIC (Smaller is Better)	12986.9
AICC (Smaller is Better)	12987.2
BIC (Smaller is Better)	13073.3

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
20	2932.55	<.0001

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRT01PN(avisitn)	6	436	2.83	0.0103
PREAD(avisitn)	6	433	1.45	0.1950
BASE(avisitn)	6	433	2.12	0.0498

Body weight after 26 weeks of treatment - change from baseline - statistical sensitivity analysis - MMRM - full analysis set - appendix

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	-1.5006	0.3729	431.5	-4.02
TRT01PN(avisitn)	Change from baseline, IDeg	WORK.ANA_DATA	1.0016	0.5315	440.4	1.88

Least Squares Means Estimates

Effect	Label	Pr > t	Alpha	Lower	Upper
TRT01PN(avisitn)	Change from baseline, IDegLira	<.0001	0.05	-2.2334	-0.7677
TRT01PN(avisitn)	Change from baseline, IDeg	0.0602	0.05	-0.04305	2.0463

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF
TRT01PN(avisitn)	Treatment contrast, IDegLira - IDeg	WORK.ANA_DATA	-2.5022	0.6506	437.4

Least Squares Means Estimate

Effect	Label	t Value	Pr > t	Alpha	Lower	Upper
TRT01PN(avisitn)	Treatment contrast, IDegLira - IDeg	-3.85	0.0001	0.05	-3.7810	-1.2234

15: Body weight after 26 weeks of treatment – change from baseline – statistical sensitivity analysis – conditional multiple imputation – full analysis set - appendix

paramsort=1 Parameter Code=C25208X Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.003073	0.055557	0.058633	362883

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.055374	0.052474	0.999948

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	76.457794	0.242143	75.98320	76.93239	362883	76.282848	76.635672

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	315.75	<.0001

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

paramsort=1 Parameter Code=C25208X Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.001029	0.027690	0.028721	776179

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.037211	0.035878	0.999964

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	75.358828	0.169471	75.02667	75.69099	776179	75.271846	75.482403

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	444.67	<.0001

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

paramsort=2 Parameter Code=WEIGHTU Label=LSMeans, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.014938	0.270027	0.284980	362883

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.055374	0.052474	0.999948

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	168.560582	0.533835	167.5143	169.6069	362883	168.174892	168.952737

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	315.75	<.0001

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

paramsort=2 Parameter Code=WEIGHTU Label=LSMeans, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_ABS_MI
Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.005003	0.134584	0.139592	776179

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.037211	0.035878	0.999964

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	166.137776	0.373621	165.4055	166.8701	776179	165.946014	166.410213

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	444.67	<.0001

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

paramsort=1 Parameter Code=C25208X Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.003073	0.055557	0.058633	362883

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.055374	0.052474	0.999948

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	0.465300	0.242143	-0.00929	0.939894	362883	0.290354	0.643178

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.92	0.0547

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

paramsort=1 Parameter Code=C25208X Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.001029	0.027690	0.028721	776179

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.037211	0.035878	0.999964

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.633667	0.169471	-0.96583	-0.30151	776179	-0.720649	-0.510092

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-3.74	0.0002

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

paramsort=1 Parameter Code=C25208X Label=Treatment contrast, IDegLira - IDeg Statement Number=2

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.003720	0.083600	0.087324	549385

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.044542	0.042646	0.999957

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.098966	0.295507	-1.67815	-0.51978	549385	-1.284088	-0.904160

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	-3.72	0.0002

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

paramsort=2 Parameter Code=WEIGHTU Label=Change from baseline, IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.014938	0.270027	0.284980	362883

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.055374	0.052474	0.999948

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	1.025810	0.533835	-0.02049	2.072111	362883	0.640120	1.417965

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	1.92	0.0547

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

paramsort=2 Parameter Code=WEIGHTU Label=Change from baseline, IDegLira Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.005003	0.134584	0.139592	776179

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.037211	0.035878	0.999964

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-1.396996	0.373621	-2.12928	-0.66471	776179	-1.588758	-1.124560

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.74	0.0002

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

paramsort=2 Parameter Code=WEIGHTU Label=Treatment contrast, IDegLira - IDeg Statement Number=2

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_CHG_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.018081	0.406328	0.424427	549385

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.044542	0.042646	0.999957

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-2.422806	0.651481	-3.69969	-1.14592	549385	-2.830930	-1.993332

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-3.72	0.0002

16: Waist circumference after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	15.5557

Fit Statistics

-2 Res Log Likelihood 2532.4
 AIC (Smaller is Better) 2534.4
 AICC (Smaller is Better) 2534.4
 BIC (Smaller is Better) 2538.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	6.1773	2.0732	449	2.98
trtpn		1	-0.8684	0.3938	449	-2.21
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3609	0.3724	449	0.97
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.9397	0.02113	449	44.48

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=MEANWAIC

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0030	0.05
trtpn		1	0.0279	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3330	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.1029	10.2517
trtpn		1	-1.6422	-0.09459
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.3710	1.0928
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.8982	0.9812

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	4.86	0.0279
PREAD	1	449	0.94	0.3330
BASE	1	449	1978.54	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	96.2124	0.2271	449	423.69	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	97.0808	0.3213	449	302.13	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	95.7661	96.6586	6.088E41	3.897E41	9.513E41
trtpn	LSMeans, IDeg	96.4493	97.7123	1.451E42	7.716E41	2.728E42

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.8684	0.3938	449	-2.21

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=MEANWAIC

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0279	0.05	-1.6422	-0.09459	0.4196

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.1935	0.9097

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	15.5557

Fit Statistics

-2 Res Log Likelihood	2532.4
AIC (Smaller is Better)	2534.4
AICC (Smaller is Better)	2534.4
BIC (Smaller is Better)	2538.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			6.1773	2.0732	449	2.98
trtpn		1	-0.8684	0.3938	449	-2.21
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.3609	0.3724	449	0.97
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.06029	0.02113	449	-2.85

Waist circumference after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=MEANWAIC

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0030	0.05
trtpn		1	0.0279	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3330	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0045	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.1029	10.2517
trtpn		1	-1.6422	-0.09459
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.3710	1.0928
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.1018	-0.01877

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	4.86	0.0279
PREAD	1	449	0.94	0.3330
BASE	1	449	8.15	0.0045

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-0.3413	0.2271	449	-1.50	0.1335
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.5271	0.3213	449	1.64	0.1016

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-0.7876	0.1049
trtpn	Change from baseline, IDeg	0.05	-0.1044	1.1585

17: Fasting plasma glucose after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2.9791

Fit Statistics

-2 Res Log Likelihood 1788.0
 AIC (Smaller is Better) 1790.0
 AICC (Smaller is Better) 1790.0
 BIC (Smaller is Better) 1794.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	5.8339	0.3212	449	18.16
trtpn		1	-0.4165	0.1722	449	-2.42
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.1213	0.1624	449	-0.75
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.1052	0.02893	449	3.64

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105585P

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4557	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0003	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			5.2026	6.4651
trtpn		1	-0.7550	-0.07803
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4405	0.1980
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.04833	0.1621

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	5.85	0.0160
PREAD	1	449	0.56	0.4557
BASE	1	449	13.22	0.0003

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	6.3857	0.09936	449	64.27	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	6.8022	0.1406	449	48.39	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	6.1904	6.5809	593.28	488.05	721.21
trtpn	LSMeans, IDeg	6.5259	7.0784	899.79	682.61	1186.08

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.4165	0.1722	449	-2.42

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105585P

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0160	0.05	-0.7550	-0.07803	0.6594

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.4700	0.9249

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	967.38

Fit Statistics

-2 Res Log Likelihood	4390.3
AIC (Smaller is Better)	4392.3
AICC (Smaller is Better)	4392.3
BIC (Smaller is Better)	4396.4

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			105.13	5.7880	449	18.16
trtpn		1	-7.5052	3.1034	449	-2.42
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.1852	2.9272	449	-0.75
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.1052	0.02893	449	3.64

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=FPGU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4557	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.0003	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			93.7515	116.50
trtpn		1	-13.6042	-1.4062
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-7.9378	3.5675
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.04833	0.1621

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	5.85	0.0160
PREAD	1	449	0.56	0.4557
BASE	1	449	13.22	0.0003

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	115.07	1.7904	449	64.27	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	122.58	2.5330	449	48.39	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	111.55	118.59	9.423E49	2.793E48	3.179E51
trtpn	LSMeans, IDeg	117.60	127.55	1.713E53	1.18E51	2.486E55

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-7.5052	3.1034	449	-2.42

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=FPGU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0160	0.05	-13.6042	-1.4062	0.000550

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	1.235E-6	0.2451

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=CL05585P

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2.9791

Fit Statistics

-2 Res Log Likelihood	1788.0
AIC (Smaller is Better)	1790.0
AICC (Smaller is Better)	1790.0
BIC (Smaller is Better)	1794.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	5.8339	0.3212	449	18.16
trtpn		1	-0.4165	0.1722	449	-2.42
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.1213	0.1624	449	-0.75
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.8948	0.02893	449	-30.93

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105585P

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4557	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			5.2026	6.4651
trtpn		1	-0.7550	-0.07803
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4405	0.1980
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.9517	-0.8379

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	5.85	0.0160
PREAD	1	449	0.56	0.4557
BASE	1	449	956.44	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-3.3662	0.09936	449	-33.88	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	-2.9497	0.1406	449	-20.98	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-3.5615	-3.1709
trtpn	Change from baseline, IDeg	0.05	-3.2260	-2.6735

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	967.38

Fit Statistics

-2 Res Log Likelihood	4390.3
AIC (Smaller is Better)	4392.3
AICC (Smaller is Better)	4392.3
BIC (Smaller is Better)	4396.4

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			105.13	5.7880	449	18.16
trtpn		1	-7.5052	3.1034	449	-2.42
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-2.1852	2.9272	449	-0.75
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.8948	0.02893	449	-30.93

Fasting plasma glucose after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=FPGU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4557	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			93.7515	116.50
trtpn		1	-13.6042	-1.4062
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-7.9378	3.5675
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.9517	-0.8379

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	5.85	0.0160
PREAD	1	449	0.56	0.4557
BASE	1	449	956.44	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-60.6590	1.7904	449	-33.88	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	-53.1538	2.5330	449	-20.98	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-64.1776	-57.1403
trtpn	Change from baseline, IDeg	0.05	-58.1318	-48.1758

18: 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

Class Level Information

Class	Levels	Values
USUBJID	453	



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

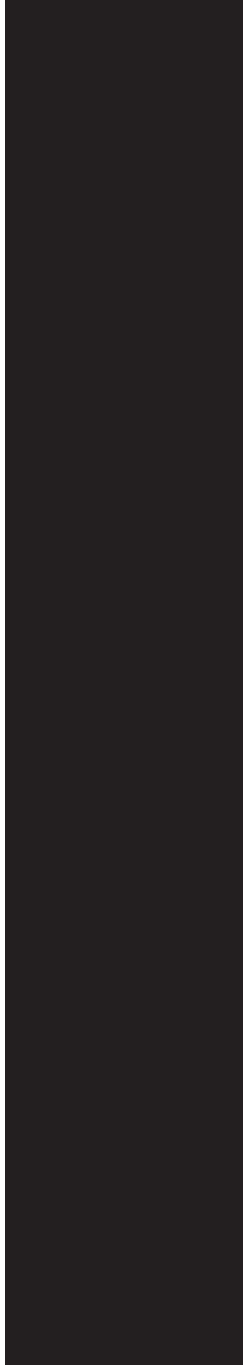
The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure



TRTPN 2 1 2
ATPTN 9 1 2 3 4 5 6 7 8 9
PREAD 2 BASAL INSULIN + METFORMIN
BASAL INSULIN + METFORMIN +
ONE OTHER OAD

Dimensions

Covariance Parameters 2
Columns in X 39
Columns in Z 0

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=C105585Y

The Mixed Procedure

Dimensions

Subjects 453
 Max Obs per Subject 9

Number of Observations

Number of Observations Read 4077
 Number of Observations Used 3987
 Number of Observations Not Used 90

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	17980.86879431	
1	2	16986.47007207	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error	Z Value	Pr > Z	Alpha	Lower	Upper
CS	USUBJID	1.9446	0.1557	12.49	<.0001	0.05	1.6394	2.2499
Residual		3.3601	0.08020	41.90	<.0001	0.05	3.2083	3.5230

Asymptotic Covariance Matrix of Estimates

Row	Cov Parm	CovP1	CovP2
1	CS	0.02425	-0.00074
2	Residual	-0.00074	0.006432

Fit Statistics

-2 Res Log Likelihood 16986.5
 AIC (Smaller is Better) 16990.5
 AICC (Smaller is Better) 16990.5
 BIC (Smaller is Better) 16998.7

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	994.40	<.0001

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period (N)	Analysis Timepoint (N)	Estimate	Standard Error
Intercept				5.9802	0.2158
TRTPN		1		-0.3993	0.2304
TRTPN		2		0	

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 treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Estimate	Standard Error
TRTPN (ATPTN)		1	1	0.03903	0.1878
TRTPN (ATPTN)		2	1	0.1496	0.2428
TRTPN (ATPTN)		1	2	3.9868	0.1890
TRTPN (ATPTN)		2	2	4.8504	0.2441
TRTPN (ATPTN)		1	3	1.2229	0.1887
TRTPN (ATPTN)		2	3	2.1036	0.2445
TRTPN (ATPTN)		1	4	4.0424	0.1883
TRTPN (ATPTN)		2	4	5.1013	0.2434
TRTPN (ATPTN)		1	5	1.8419	0.1886
TRTPN (ATPTN)		2	5	2.1763	0.2442
TRTPN (ATPTN)		1	6	4.4428	0.1885
TRTPN (ATPTN)		2	6	5.0832	0.2451
TRTPN (ATPTN)		1	7	3.0157	0.1906
TRTPN (ATPTN)		2	7	3.6866	0.2462
TRTPN (ATPTN)		1	8	0.4344	0.1905
TRTPN (ATPTN)		2	8	0.7451	0.2450
TRTPN (ATPTN)		1	9	0	
TRTPN (ATPTN)		2	9	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		1	-0.1512	0.2168
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		1	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		2	-0.03748	0.2188
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		2	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		3	0.3374	0.2187
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		3	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		4	0.2126	0.2180
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		4	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		5	-0.1693	0.2183
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		5	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		6	-0.09171	0.2191
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		6	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		7	0.05532	0.2205
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		7	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		8	-0.05872	0.2204
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		8	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		9	-0.02011	0.2172
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		9	0	

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	DF	t Value
Intercept				1934	27.71
TRTPN		1		1940	-1.73
TRTPN		2			
TRTPN (ATPTN)		1	1	3512	0.21
TRTPN (ATPTN)		2	1	3513	0.62
TRTPN (ATPTN)		1	2	3516	21.09
TRTPN (ATPTN)		2	2	3514	19.87
TRTPN (ATPTN)		1	3	3515	6.48
TRTPN (ATPTN)		2	3	3516	8.60
TRTPN (ATPTN)		1	4	3514	21.47
TRTPN (ATPTN)		2	4	3513	20.96
TRTPN (ATPTN)		1	5	3515	9.77
TRTPN (ATPTN)		2	5	3515	8.91
TRTPN (ATPTN)		1	6	3515	23.57

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 treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	DF	t Value
TRTPN (ATPTN)		2	6	3516	20.74
TRTPN (ATPTN)		1	7	3518	15.82
TRTPN (ATPTN)		2	7	3517	14.98
TRTPN (ATPTN)		1	8	3518	2.28
TRTPN (ATPTN)		2	8	3516	3.04
TRTPN (ATPTN)		1	9		
TRTPN (ATPTN)		2	9		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		1	1927	-0.70
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		1		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		2	1970	-0.17
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		2		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		3	1965	1.54
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		3		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		4	1949	0.98
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		4		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		5	1956	-0.78
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		5		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		6	1975	-0.42
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		6		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		7	2009	0.25
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		7		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		8	2006	-0.27
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		8		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		9	1934	-0.09
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		9		

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Pr > t
Intercept				<.0001
TRTPN		1		0.0833
TRTPN		2		
TRTPN (ATPTN)		1	1	0.8354
TRTPN (ATPTN)		2	1	0.5380
TRTPN (ATPTN)		1	2	<.0001
TRTPN (ATPTN)		2	2	<.0001
TRTPN (ATPTN)		1	3	<.0001
TRTPN (ATPTN)		2	3	<.0001
TRTPN (ATPTN)		1	4	<.0001
TRTPN (ATPTN)		2	4	<.0001
TRTPN (ATPTN)		1	5	<.0001
TRTPN (ATPTN)		2	5	<.0001
TRTPN (ATPTN)		1	6	<.0001
TRTPN (ATPTN)		2	6	<.0001
TRTPN (ATPTN)		1	7	<.0001
TRTPN (ATPTN)		2	7	<.0001
TRTPN (ATPTN)		1	8	0.0227
TRTPN (ATPTN)		2	8	0.0024
TRTPN (ATPTN)		1	9	
TRTPN (ATPTN)		2	9	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		1	0.4855
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		1	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		2	0.8640
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		2	

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=Cl05585Y

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Pr > t
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		3	0.1230
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		3	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		4	0.3295
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		4	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		5	0.4381
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		5	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		6	0.6755
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		6	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		7	0.8020
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		7	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		8	0.7900
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		8	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		9	0.9262
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		9	

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	1	451	38.01	<.0001
TRTPN(ATPTN)	8	3517	3.99	0.0001
PREAD(ATPTN)	9	3357	0.83	0.5889

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	5.5482	0.1325	1927	41.86	<.0001
TRTPN(ATPTN)	2	1	WORK.ANA_DATA	6.0580	0.1875	1927	32.32	<.0001
TRTPN(ATPTN)	1	2	WORK.ANA_DATA	9.5499	0.1332	1950	71.70	<.0001
TRTPN(ATPTN)	2	2	WORK.ANA_DATA	10.8128	0.1909	2006	56.65	<.0001
TRTPN(ATPTN)	1	3	WORK.ANA_DATA	6.9640	0.1330	1943	52.34	<.0001
TRTPN(ATPTN)	2	3	WORK.ANA_DATA	8.2440	0.1909	2006	43.20	<.0001
TRTPN(ATPTN)	1	4	WORK.ANA_DATA	9.7242	0.1331	1944	73.08	<.0001

Least Squares Means

Effect	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Alpha	Lower	Upper
TRTPN(ATPTN)	1	1	0.05	5.2882	5.8081
TRTPN(ATPTN)	2	1	0.05	5.6903	6.4256
TRTPN(ATPTN)	1	2	0.05	9.2887	9.8111
TRTPN(ATPTN)	2	2	0.05	10.4385	11.1871
TRTPN(ATPTN)	1	3	0.05	6.7030	7.2249
TRTPN(ATPTN)	2	3	0.05	7.8697	8.6182
TRTPN(ATPTN)	1	4	0.05	9.4632	9.9851

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)	2	4	WORK.ANA_DATA	11.1823	0.1890	1957	59.18	<.0001
TRTPN (ATPTN)	1	5	WORK.ANA_DATA	7.3424	0.1330	1943	55.19	<.0001
TRTPN (ATPTN)	2	5	WORK.ANA_DATA	8.0761	0.1899	1981	42.52	<.0001
TRTPN (ATPTN)	1	6	WORK.ANA_DATA	9.9802	0.1332	1950	74.92	<.0001
TRTPN (ATPTN)	2	6	WORK.ANA_DATA	11.0199	0.1913	2018	57.60	<.0001
TRTPN (ATPTN)	1	7	WORK.ANA_DATA	8.6229	0.1343	1992	64.20	<.0001
TRTPN (ATPTN)	2	7	WORK.ANA_DATA	9.6930	0.1923	2044	50.41	<.0001
TRTPN (ATPTN)	1	8	WORK.ANA_DATA	5.9875	0.1345	1998	44.52	<.0001
TRTPN (ATPTN)	2	8	WORK.ANA_DATA	6.6974	0.1914	2018	35.00	<.0001
TRTPN (ATPTN)	1	9	WORK.ANA_DATA	5.5714	0.1325	1927	42.03	<.0001
TRTPN (ATPTN)	2	9	WORK.ANA_DATA	5.9706	0.1884	1947	31.69	<.0001

Least Squares Means

Effect	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Alpha	Lower	Upper
TRTPN (ATPTN)	2	4	0.05	10.8118	11.5529
TRTPN (ATPTN)	1	5	0.05	7.0815	7.6034
TRTPN (ATPTN)	2	5	0.05	7.7036	8.4486
TRTPN (ATPTN)	1	6	0.05	9.7190	10.2415
TRTPN (ATPTN)	2	6	0.05	10.6446	11.3951
TRTPN (ATPTN)	1	7	0.05	8.3594	8.8863
TRTPN (ATPTN)	2	7	0.05	9.3159	10.0701
TRTPN (ATPTN)	1	8	0.05	5.7237	6.2512
TRTPN (ATPTN)	2	8	0.05	6.3221	7.0727
TRTPN (ATPTN)	1	9	0.05	5.3114	5.8313
TRTPN (ATPTN)	2	9	0.05	5.6011	6.3402

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	-0.5098	0.2296	1927
TRTPN (ATPTN)	1	1	1	2	WORK.ANA_DATA	-4.0018	0.1498	3513
TRTPN (ATPTN)	1	1	2	2	WORK.ANA_DATA	-5.2646	0.2324	1979
TRTPN (ATPTN)	1	1	1	3	WORK.ANA_DATA	-1.4158	0.1496	3514
TRTPN (ATPTN)	1	1	2	3	WORK.ANA_DATA	-2.6958	0.2324	1979
TRTPN (ATPTN)	1	1	1	4	WORK.ANA_DATA	-4.1760	0.1496	3514
TRTPN (ATPTN)	1	1	2	4	WORK.ANA_DATA	-5.6342	0.2308	1947
TRTPN (ATPTN)	1	1	1	5	WORK.ANA_DATA	-1.7943	0.1496	3514
TRTPN (ATPTN)	1	1	2	5	WORK.ANA_DATA	-2.5279	0.2316	1963
TRTPN (ATPTN)	1	1	1	6	WORK.ANA_DATA	-4.4321	0.1498	3514
TRTPN (ATPTN)	1	1	2	6	WORK.ANA_DATA	-5.4717	0.2328	1988
TRTPN (ATPTN)	1	1	1	7	WORK.ANA_DATA	-3.0747	0.1508	3516
TRTPN (ATPTN)	1	1	2	7	WORK.ANA_DATA	-4.1448	0.2336	2005
TRTPN (ATPTN)	1	1	1	8	WORK.ANA_DATA	-0.4393	0.1509	3516
TRTPN (ATPTN)	1	1	2	8	WORK.ANA_DATA	-1.1492	0.2328	1988
TRTPN (ATPTN)	1	1	1	9	WORK.ANA_DATA	-0.02320	0.1492	3511
TRTPN (ATPTN)	1	1	2	9	WORK.ANA_DATA	-0.4225	0.2304	1940
TRTPN (ATPTN)	2	1	1	2	WORK.ANA_DATA	-3.4920	0.2300	1934

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	1	2	2	WORK.ANA_DATA	-4.7548	0.2140	3526
TRTPN (ATPTN)	2	1	1	3	WORK.ANA_DATA	-0.9060	0.2299	1932
TRTPN (ATPTN)	2	1	2	3	WORK.ANA_DATA	-2.1860	0.2140	3526
TRTPN (ATPTN)	2	1	1	4	WORK.ANA_DATA	-3.6662	0.2299	1932
TRTPN (ATPTN)	2	1	2	4	WORK.ANA_DATA	-5.1244	0.2123	3522
TRTPN (ATPTN)	2	1	1	5	WORK.ANA_DATA	-1.2845	0.2299	1932
TRTPN (ATPTN)	2	1	2	5	WORK.ANA_DATA	-2.0181	0.2132	3525
TRTPN (ATPTN)	2	1	1	6	WORK.ANA_DATA	-3.9223	0.2300	1934
TRTPN (ATPTN)	2	1	2	6	WORK.ANA_DATA	-4.9619	0.2144	3527
TRTPN (ATPTN)	2	1	1	7	WORK.ANA_DATA	-2.5649	0.2306	1948
TRTPN (ATPTN)	2	1	2	7	WORK.ANA_DATA	-3.6350	0.2153	3528
TRTPN (ATPTN)	2	1	1	8	WORK.ANA_DATA	0.07050	0.2307	1950
TRTPN (ATPTN)	2	1	2	8	WORK.ANA_DATA	-0.6394	0.2145	3527
TRTPN (ATPTN)	2	1	1	9	WORK.ANA_DATA	0.4866	0.2296	1926
TRTPN (ATPTN)	2	1	2	9	WORK.ANA_DATA	0.08734	0.2119	3517
TRTPN (ATPTN)	1	2	2	2	WORK.ANA_DATA	-1.2629	0.2327	1987
TRTPN (ATPTN)	1	2	1	3	WORK.ANA_DATA	2.5860	0.1501	3513
TRTPN (ATPTN)	1	2	2	3	WORK.ANA_DATA	1.3060	0.2327	1987
TRTPN (ATPTN)	1	2	1	4	WORK.ANA_DATA	-0.1742	0.1501	3513
TRTPN (ATPTN)	1	2	2	4	WORK.ANA_DATA	-1.6324	0.2312	1954
TRTPN (ATPTN)	1	2	1	5	WORK.ANA_DATA	2.2075	0.1501	3513
TRTPN (ATPTN)	1	2	2	5	WORK.ANA_DATA	1.4738	0.2320	1970
TRTPN (ATPTN)	1	2	1	6	WORK.ANA_DATA	-0.4303	0.1503	3513
TRTPN (ATPTN)	1	2	2	6	WORK.ANA_DATA	-1.4699	0.2331	1995
TRTPN (ATPTN)	1	2	1	7	WORK.ANA_DATA	0.9271	0.1513	3515
TRTPN (ATPTN)	1	2	2	7	WORK.ANA_DATA	-0.1431	0.2339	2013
TRTPN (ATPTN)	1	2	1	8	WORK.ANA_DATA	3.5625	0.1514	3515
TRTPN (ATPTN)	1	2	2	8	WORK.ANA_DATA	2.8525	0.2331	1995
TRTPN (ATPTN)	1	2	1	9	WORK.ANA_DATA	3.9786	0.1498	3513
TRTPN (ATPTN)	1	2	2	9	WORK.ANA_DATA	3.5793	0.2308	1947
TRTPN (ATPTN)	2	2	1	3	WORK.ANA_DATA	3.8488	0.2327	1985
TRTPN (ATPTN)	2	2	2	3	WORK.ANA_DATA	2.5689	0.2163	3516
TRTPN (ATPTN)	2	2	1	4	WORK.ANA_DATA	1.0886	0.2327	1985
TRTPN (ATPTN)	2	2	2	4	WORK.ANA_DATA	-0.3695	0.2148	3515
TRTPN (ATPTN)	2	2	1	5	WORK.ANA_DATA	3.4704	0.2327	1985
TRTPN (ATPTN)	2	2	2	5	WORK.ANA_DATA	2.7367	0.2156	3516
TRTPN (ATPTN)	2	2	1	6	WORK.ANA_DATA	0.8326	0.2328	1987
TRTPN (ATPTN)	2	2	2	6	WORK.ANA_DATA	-0.2071	0.2166	3514
TRTPN (ATPTN)	2	2	1	7	WORK.ANA_DATA	2.1900	0.2334	2001
TRTPN (ATPTN)	2	2	2	7	WORK.ANA_DATA	1.1198	0.2175	3515
TRTPN (ATPTN)	2	2	1	8	WORK.ANA_DATA	4.8253	0.2335	2003
TRTPN (ATPTN)	2	2	2	8	WORK.ANA_DATA	4.1154	0.2167	3516
TRTPN (ATPTN)	2	2	1	9	WORK.ANA_DATA	5.2414	0.2324	1979
TRTPN (ATPTN)	2	2	2	9	WORK.ANA_DATA	4.8422	0.2146	3520
TRTPN (ATPTN)	1	3	2	3	WORK.ANA_DATA	-1.2800	0.2327	1985
TRTPN (ATPTN)	1	3	1	4	WORK.ANA_DATA	-2.7602	0.1500	3511
TRTPN (ATPTN)	1	3	2	4	WORK.ANA_DATA	-4.2184	0.2311	1952
TRTPN (ATPTN)	1	3	1	5	WORK.ANA_DATA	-0.3785	0.1500	3511
TRTPN (ATPTN)	1	3	2	5	WORK.ANA_DATA	-1.1121	0.2319	1968
TRTPN (ATPTN)	1	3	1	6	WORK.ANA_DATA	-3.0163	0.1501	3512
TRTPN (ATPTN)	1	3	2	6	WORK.ANA_DATA	-4.0559	0.2330	1993
TRTPN (ATPTN)	1	3	1	7	WORK.ANA_DATA	-1.6589	0.1511	3513
TRTPN (ATPTN)	1	3	2	7	WORK.ANA_DATA	-2.7290	0.2338	2011
TRTPN (ATPTN)	1	3	1	8	WORK.ANA_DATA	0.9765	0.1512	3514
TRTPN (ATPTN)	1	3	2	8	WORK.ANA_DATA	0.2666	0.2331	1993
TRTPN (ATPTN)	1	3	1	9	WORK.ANA_DATA	1.3926	0.1496	3514
TRTPN (ATPTN)	1	3	2	9	WORK.ANA_DATA	0.9933	0.2307	1945
TRTPN (ATPTN)	2	3	1	4	WORK.ANA_DATA	-1.4802	0.2327	1985
TRTPN (ATPTN)	2	3	2	4	WORK.ANA_DATA	-2.9384	0.2149	3518

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	3	1	5	WORK.ANA_DATA	0.9015	0.2327	1985
TRTPN (ATPTN)	2	3	2	5	WORK.ANA_DATA	0.1679	0.2154	3512
TRTPN (ATPTN)	2	3	1	6	WORK.ANA_DATA	-1.7363	0.2328	1987
TRTPN (ATPTN)	2	3	2	6	WORK.ANA_DATA	-2.7759	0.2167	3516
TRTPN (ATPTN)	2	3	1	7	WORK.ANA_DATA	-0.3789	0.2334	2001
TRTPN (ATPTN)	2	3	2	7	WORK.ANA_DATA	-1.4490	0.2176	3518
TRTPN (ATPTN)	2	3	1	8	WORK.ANA_DATA	2.2565	0.2335	2003
TRTPN (ATPTN)	2	3	2	8	WORK.ANA_DATA	1.5466	0.2166	3513
TRTPN (ATPTN)	2	3	1	9	WORK.ANA_DATA	2.6726	0.2324	1979
TRTPN (ATPTN)	2	3	2	9	WORK.ANA_DATA	2.2733	0.2146	3520
TRTPN (ATPTN)	1	4	2	4	WORK.ANA_DATA	-1.4582	0.2311	1952
TRTPN (ATPTN)	1	4	1	5	WORK.ANA_DATA	2.3817	0.1500	3511
TRTPN (ATPTN)	1	4	2	5	WORK.ANA_DATA	1.6481	0.2319	1968
TRTPN (ATPTN)	1	4	1	6	WORK.ANA_DATA	-0.2561	0.1501	3511
TRTPN (ATPTN)	1	4	2	6	WORK.ANA_DATA	-1.2957	0.2331	1993
TRTPN (ATPTN)	1	4	1	7	WORK.ANA_DATA	1.1013	0.1511	3514
TRTPN (ATPTN)	1	4	2	7	WORK.ANA_DATA	0.03118	0.2338	2011
TRTPN (ATPTN)	1	4	1	8	WORK.ANA_DATA	3.7367	0.1512	3514
TRTPN (ATPTN)	1	4	2	8	WORK.ANA_DATA	3.0268	0.2331	1993
TRTPN (ATPTN)	1	4	1	9	WORK.ANA_DATA	4.1528	0.1496	3514
TRTPN (ATPTN)	1	4	2	9	WORK.ANA_DATA	3.7535	0.2307	1945
TRTPN (ATPTN)	2	4	1	5	WORK.ANA_DATA	3.8399	0.2311	1952
TRTPN (ATPTN)	2	4	2	5	WORK.ANA_DATA	3.1062	0.2141	3517
TRTPN (ATPTN)	2	4	1	6	WORK.ANA_DATA	1.2021	0.2312	1954
TRTPN (ATPTN)	2	4	2	6	WORK.ANA_DATA	0.1625	0.2152	3516
TRTPN (ATPTN)	2	4	1	7	WORK.ANA_DATA	2.5595	0.2318	1968
TRTPN (ATPTN)	2	4	2	7	WORK.ANA_DATA	1.4894	0.2160	3517
TRTPN (ATPTN)	2	4	1	8	WORK.ANA_DATA	5.1949	0.2319	1970
TRTPN (ATPTN)	2	4	2	8	WORK.ANA_DATA	4.4850	0.2152	3516
TRTPN (ATPTN)	2	4	1	9	WORK.ANA_DATA	5.6110	0.2308	1947
TRTPN (ATPTN)	2	4	2	9	WORK.ANA_DATA	5.2117	0.2129	3516
TRTPN (ATPTN)	1	5	2	5	WORK.ANA_DATA	-0.7336	0.2319	1968
TRTPN (ATPTN)	1	5	1	6	WORK.ANA_DATA	-2.6378	0.1501	3512
TRTPN (ATPTN)	1	5	2	6	WORK.ANA_DATA	-3.6774	0.2330	1993
TRTPN (ATPTN)	1	5	1	7	WORK.ANA_DATA	-1.2804	0.1511	3513
TRTPN (ATPTN)	1	5	2	7	WORK.ANA_DATA	-2.3505	0.2338	2011
TRTPN (ATPTN)	1	5	1	8	WORK.ANA_DATA	1.3550	0.1512	3513
TRTPN (ATPTN)	1	5	2	8	WORK.ANA_DATA	0.6451	0.2331	1993
TRTPN (ATPTN)	1	5	1	9	WORK.ANA_DATA	1.7711	0.1496	3514
TRTPN (ATPTN)	1	5	2	9	WORK.ANA_DATA	1.3718	0.2307	1945
TRTPN (ATPTN)	2	5	1	6	WORK.ANA_DATA	-1.9041	0.2320	1970
TRTPN (ATPTN)	2	5	2	6	WORK.ANA_DATA	-2.9438	0.2159	3515
TRTPN (ATPTN)	2	5	1	7	WORK.ANA_DATA	-0.5468	0.2326	1984
TRTPN (ATPTN)	2	5	2	7	WORK.ANA_DATA	-1.6169	0.2168	3516
TRTPN (ATPTN)	2	5	1	8	WORK.ANA_DATA	2.0886	0.2327	1986
TRTPN (ATPTN)	2	5	2	8	WORK.ANA_DATA	1.3787	0.2158	3513
TRTPN (ATPTN)	2	5	1	9	WORK.ANA_DATA	2.5047	0.2316	1963
TRTPN (ATPTN)	2	5	2	9	WORK.ANA_DATA	2.1055	0.2138	3519
TRTPN (ATPTN)	1	6	2	6	WORK.ANA_DATA	-1.0396	0.2331	1995
TRTPN (ATPTN)	1	6	1	7	WORK.ANA_DATA	1.3574	0.1512	3514
TRTPN (ATPTN)	1	6	2	7	WORK.ANA_DATA	0.2872	0.2339	2013
TRTPN (ATPTN)	1	6	1	8	WORK.ANA_DATA	3.9928	0.1514	3514
TRTPN (ATPTN)	1	6	2	8	WORK.ANA_DATA	3.2828	0.2332	1995
TRTPN (ATPTN)	1	6	1	9	WORK.ANA_DATA	4.4089	0.1498	3514
TRTPN (ATPTN)	1	6	2	9	WORK.ANA_DATA	4.0096	0.2308	1947
TRTPN (ATPTN)	2	6	1	7	WORK.ANA_DATA	2.3970	0.2338	2009
TRTPN (ATPTN)	2	6	2	7	WORK.ANA_DATA	1.3269	0.2180	3518
TRTPN (ATPTN)	2	6	1	8	WORK.ANA_DATA	5.0324	0.2339	2011
TRTPN (ATPTN)	2	6	2	8	WORK.ANA_DATA	4.3225	0.2170	3515

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	5.4485	0.2328	1988
TRTPN (ATPTN)	2	6	2	9	WORK.ANA_DATA	5.0492	0.2150	3521
TRTPN (ATPTN)	1	7	2	7	WORK.ANA_DATA	-1.0701	0.2346	2026
TRTPN (ATPTN)	1	7	1	8	WORK.ANA_DATA	2.6354	0.1523	3514
TRTPN (ATPTN)	1	7	2	8	WORK.ANA_DATA	1.9255	0.2338	2009
TRTPN (ATPTN)	1	7	1	9	WORK.ANA_DATA	3.0515	0.1508	3516
TRTPN (ATPTN)	1	7	2	9	WORK.ANA_DATA	2.6522	0.2314	1961
TRTPN (ATPTN)	2	7	1	8	WORK.ANA_DATA	3.7055	0.2347	2029
TRTPN (ATPTN)	2	7	2	8	WORK.ANA_DATA	2.9956	0.2179	3516
TRTPN (ATPTN)	2	7	1	9	WORK.ANA_DATA	4.1216	0.2336	2005
TRTPN (ATPTN)	2	7	2	9	WORK.ANA_DATA	3.7224	0.2159	3522
TRTPN (ATPTN)	1	8	2	8	WORK.ANA_DATA	-0.7099	0.2339	2011
TRTPN (ATPTN)	1	8	1	9	WORK.ANA_DATA	0.4161	0.1509	3516
TRTPN (ATPTN)	1	8	2	9	WORK.ANA_DATA	0.01684	0.2315	1964
TRTPN (ATPTN)	2	8	1	9	WORK.ANA_DATA	1.1260	0.2328	1988
TRTPN (ATPTN)	2	8	2	9	WORK.ANA_DATA	0.7268	0.2151	3522
TRTPN (ATPTN)	1	9	2	9	WORK.ANA_DATA	-0.3993	0.2304	1940

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	-2.22	0.0265	0.05
TRTPN (ATPTN)	1	1	1	2	-26.72	<.0001	0.05
TRTPN (ATPTN)	1	1	2	2	-22.66	<.0001	0.05
TRTPN (ATPTN)	1	1	1	3	-9.46	<.0001	0.05
TRTPN (ATPTN)	1	1	2	3	-11.60	<.0001	0.05
TRTPN (ATPTN)	1	1	1	4	-27.91	<.0001	0.05
TRTPN (ATPTN)	1	1	2	4	-24.41	<.0001	0.05
TRTPN (ATPTN)	1	1	1	5	-11.99	<.0001	0.05
TRTPN (ATPTN)	1	1	2	5	-10.91	<.0001	0.05
TRTPN (ATPTN)	1	1	1	6	-29.59	<.0001	0.05
TRTPN (ATPTN)	1	1	2	6	-23.51	<.0001	0.05
TRTPN (ATPTN)	1	1	1	7	-20.39	<.0001	0.05
TRTPN (ATPTN)	1	1	2	7	-17.75	<.0001	0.05
TRTPN (ATPTN)	1	1	1	8	-2.91	0.0036	0.05
TRTPN (ATPTN)	1	1	2	8	-4.94	<.0001	0.05
TRTPN (ATPTN)	1	1	1	9	-0.16	0.8764	0.05
TRTPN (ATPTN)	1	1	2	9	-1.83	0.0669	0.05
TRTPN (ATPTN)	2	1	1	2	-15.18	<.0001	0.05
TRTPN (ATPTN)	2	1	2	2	-22.22	<.0001	0.05
TRTPN (ATPTN)	2	1	1	3	-3.94	<.0001	0.05
TRTPN (ATPTN)	2	1	2	3	-10.21	<.0001	0.05
TRTPN (ATPTN)	2	1	1	4	-15.95	<.0001	0.05
TRTPN (ATPTN)	2	1	2	4	-24.13	<.0001	0.05
TRTPN (ATPTN)	2	1	1	5	-5.59	<.0001	0.05
TRTPN (ATPTN)	2	1	2	5	-9.47	<.0001	0.05
TRTPN (ATPTN)	2	1	1	6	-17.05	<.0001	0.05
TRTPN (ATPTN)	2	1	2	6	-23.14	<.0001	0.05
TRTPN (ATPTN)	2	1	1	7	-11.12	<.0001	0.05
TRTPN (ATPTN)	2	1	2	7	-16.88	<.0001	0.05
TRTPN (ATPTN)	2	1	1	8	0.31	0.7600	0.05
TRTPN (ATPTN)	2	1	2	8	-2.98	0.0029	0.05
TRTPN (ATPTN)	2	1	1	9	2.12	0.0342	0.05
TRTPN (ATPTN)	2	1	2	9	0.41	0.6802	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)	1	2	2	2	-5.43	<.0001	0.05
TRTPN (ATPTN)	1	2	1	3	17.22	<.0001	0.05
TRTPN (ATPTN)	1	2	2	3	5.61	<.0001	0.05
TRTPN (ATPTN)	1	2	1	4	-1.16	0.2459	0.05
TRTPN (ATPTN)	1	2	2	4	-7.06	<.0001	0.05
TRTPN (ATPTN)	1	2	1	5	14.70	<.0001	0.05
TRTPN (ATPTN)	1	2	2	5	6.35	<.0001	0.05
TRTPN (ATPTN)	1	2	1	6	-2.86	0.0042	0.05
TRTPN (ATPTN)	1	2	2	6	-6.31	<.0001	0.05
TRTPN (ATPTN)	1	2	1	7	6.13	<.0001	0.05
TRTPN (ATPTN)	1	2	2	7	-0.61	0.5409	0.05
TRTPN (ATPTN)	1	2	1	8	23.53	<.0001	0.05
TRTPN (ATPTN)	1	2	2	8	12.24	<.0001	0.05
TRTPN (ATPTN)	1	2	1	9	26.57	<.0001	0.05
TRTPN (ATPTN)	1	2	2	9	15.51	<.0001	0.05
TRTPN (ATPTN)	2	2	1	3	16.54	<.0001	0.05
TRTPN (ATPTN)	2	2	2	3	11.87	<.0001	0.05
TRTPN (ATPTN)	2	2	1	4	4.68	<.0001	0.05
TRTPN (ATPTN)	2	2	2	4	-1.72	0.0854	0.05
TRTPN (ATPTN)	2	2	1	5	14.92	<.0001	0.05
TRTPN (ATPTN)	2	2	2	5	12.69	<.0001	0.05
TRTPN (ATPTN)	2	2	1	6	3.58	0.0004	0.05
TRTPN (ATPTN)	2	2	2	6	-0.96	0.3392	0.05
TRTPN (ATPTN)	2	2	1	7	9.38	<.0001	0.05
TRTPN (ATPTN)	2	2	2	7	5.15	<.0001	0.05
TRTPN (ATPTN)	2	2	1	8	20.67	<.0001	0.05
TRTPN (ATPTN)	2	2	2	8	18.99	<.0001	0.05
TRTPN (ATPTN)	2	2	1	9	22.56	<.0001	0.05
TRTPN (ATPTN)	2	2	2	9	22.56	<.0001	0.05
TRTPN (ATPTN)	1	3	2	3	-5.50	<.0001	0.05
TRTPN (ATPTN)	1	3	1	4	-18.41	<.0001	0.05
TRTPN (ATPTN)	1	3	2	4	-18.25	<.0001	0.05
TRTPN (ATPTN)	1	3	1	5	-2.52	0.0117	0.05
TRTPN (ATPTN)	1	3	2	5	-4.80	<.0001	0.05
TRTPN (ATPTN)	1	3	1	6	-20.09	<.0001	0.05
TRTPN (ATPTN)	1	3	2	6	-17.40	<.0001	0.05
TRTPN (ATPTN)	1	3	1	7	-10.98	<.0001	0.05
TRTPN (ATPTN)	1	3	2	7	-11.67	<.0001	0.05
TRTPN (ATPTN)	1	3	1	8	6.46	<.0001	0.05
TRTPN (ATPTN)	1	3	2	8	1.14	0.2528	0.05
TRTPN (ATPTN)	1	3	1	9	9.31	<.0001	0.05
TRTPN (ATPTN)	1	3	2	9	4.31	<.0001	0.05
TRTPN (ATPTN)	2	3	1	4	-6.36	<.0001	0.05
TRTPN (ATPTN)	2	3	2	4	-13.67	<.0001	0.05
TRTPN (ATPTN)	2	3	1	5	3.87	0.0001	0.05
TRTPN (ATPTN)	2	3	2	5	0.78	0.4358	0.05
TRTPN (ATPTN)	2	3	1	6	-7.46	<.0001	0.05
TRTPN (ATPTN)	2	3	2	6	-12.81	<.0001	0.05
TRTPN (ATPTN)	2	3	1	7	-1.62	0.1046	0.05
TRTPN (ATPTN)	2	3	2	7	-6.66	<.0001	0.05
TRTPN (ATPTN)	2	3	1	8	9.66	<.0001	0.05
TRTPN (ATPTN)	2	3	2	8	7.14	<.0001	0.05
TRTPN (ATPTN)	2	3	1	9	11.50	<.0001	0.05
TRTPN (ATPTN)	2	3	2	9	10.59	<.0001	0.05
TRTPN (ATPTN)	1	4	2	4	-6.31	<.0001	0.05
TRTPN (ATPTN)	1	4	1	5	15.88	<.0001	0.05
TRTPN (ATPTN)	1	4	2	5	7.11	<.0001	0.05
TRTPN (ATPTN)	1	4	1	6	-1.71	0.0881	0.05
TRTPN (ATPTN)	1	4	2	6	-5.56	<.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)	1	4	1	7	7.29	<.0001	0.05
TRTPN (ATPTN)	1	4	2	7	0.13	0.8939	0.05
TRTPN (ATPTN)	1	4	1	8	24.71	<.0001	0.05
TRTPN (ATPTN)	1	4	2	8	12.99	<.0001	0.05
TRTPN (ATPTN)	1	4	1	9	27.75	<.0001	0.05
TRTPN (ATPTN)	1	4	2	9	16.27	<.0001	0.05
TRTPN (ATPTN)	2	4	1	5	16.62	<.0001	0.05
TRTPN (ATPTN)	2	4	2	5	14.51	<.0001	0.05
TRTPN (ATPTN)	2	4	1	6	5.20	<.0001	0.05
TRTPN (ATPTN)	2	4	2	6	0.75	0.4503	0.05
TRTPN (ATPTN)	2	4	1	7	11.04	<.0001	0.05
TRTPN (ATPTN)	2	4	2	7	6.89	<.0001	0.05
TRTPN (ATPTN)	2	4	1	8	22.40	<.0001	0.05
TRTPN (ATPTN)	2	4	2	8	20.84	<.0001	0.05
TRTPN (ATPTN)	2	4	1	9	24.31	<.0001	0.05
TRTPN (ATPTN)	2	4	2	9	24.48	<.0001	0.05
TRTPN (ATPTN)	1	5	2	5	-3.16	0.0016	0.05
TRTPN (ATPTN)	1	5	1	6	-17.57	<.0001	0.05
TRTPN (ATPTN)	1	5	2	6	-15.78	<.0001	0.05
TRTPN (ATPTN)	1	5	1	7	-8.48	<.0001	0.05
TRTPN (ATPTN)	1	5	2	7	-10.05	<.0001	0.05
TRTPN (ATPTN)	1	5	1	8	8.96	<.0001	0.05
TRTPN (ATPTN)	1	5	2	8	2.77	0.0057	0.05
TRTPN (ATPTN)	1	5	1	9	11.84	<.0001	0.05
TRTPN (ATPTN)	1	5	2	9	5.95	<.0001	0.05
TRTPN (ATPTN)	2	5	1	6	-8.21	<.0001	0.05
TRTPN (ATPTN)	2	5	2	6	-13.63	<.0001	0.05
TRTPN (ATPTN)	2	5	1	7	-2.35	0.0189	0.05
TRTPN (ATPTN)	2	5	2	7	-7.46	<.0001	0.05
TRTPN (ATPTN)	2	5	1	8	8.97	<.0001	0.05
TRTPN (ATPTN)	2	5	2	8	6.39	<.0001	0.05
TRTPN (ATPTN)	2	5	1	9	10.81	<.0001	0.05
TRTPN (ATPTN)	2	5	2	9	9.85	<.0001	0.05
TRTPN (ATPTN)	1	6	2	6	-4.46	<.0001	0.05
TRTPN (ATPTN)	1	6	1	7	8.98	<.0001	0.05
TRTPN (ATPTN)	1	6	2	7	1.23	0.2196	0.05
TRTPN (ATPTN)	1	6	1	8	26.38	<.0001	0.05
TRTPN (ATPTN)	1	6	2	8	14.08	<.0001	0.05
TRTPN (ATPTN)	1	6	1	9	29.44	<.0001	0.05
TRTPN (ATPTN)	1	6	2	9	17.38	<.0001	0.05
TRTPN (ATPTN)	2	6	1	7	10.25	<.0001	0.05
TRTPN (ATPTN)	2	6	2	7	6.09	<.0001	0.05
TRTPN (ATPTN)	2	6	1	8	21.52	<.0001	0.05
TRTPN (ATPTN)	2	6	2	8	19.91	<.0001	0.05
TRTPN (ATPTN)	2	6	1	9	23.41	<.0001	0.05
TRTPN (ATPTN)	2	6	2	9	23.48	<.0001	0.05
TRTPN (ATPTN)	1	7	2	7	-4.56	<.0001	0.05
TRTPN (ATPTN)	1	7	1	8	17.31	<.0001	0.05
TRTPN (ATPTN)	1	7	2	8	8.24	<.0001	0.05
TRTPN (ATPTN)	1	7	1	9	20.24	<.0001	0.05
TRTPN (ATPTN)	1	7	2	9	11.46	<.0001	0.05
TRTPN (ATPTN)	2	7	1	8	15.79	<.0001	0.05
TRTPN (ATPTN)	2	7	2	8	13.75	<.0001	0.05
TRTPN (ATPTN)	2	7	1	9	17.65	<.0001	0.05
TRTPN (ATPTN)	2	7	2	9	17.24	<.0001	0.05
TRTPN (ATPTN)	1	8	2	8	-3.04	0.0024	0.05
TRTPN (ATPTN)	1	8	1	9	2.76	0.0059	0.05
TRTPN (ATPTN)	1	8	2	9	0.07	0.9420	0.05
TRTPN (ATPTN)	2	8	1	9	4.84	<.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	8	2	9	3.38	0.0007	0.05
TRTPN (ATPTN)	1	9	2	9	-1.73	0.0833	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	-0.9601	-0.05948
TRTPN (ATPTN)	1	1	1	2	-4.2954	-3.7081
TRTPN (ATPTN)	1	1	2	2	-5.7204	-4.8089
TRTPN (ATPTN)	1	1	1	3	-1.7092	-1.1224
TRTPN (ATPTN)	1	1	2	3	-3.1515	-2.2401
TRTPN (ATPTN)	1	1	1	4	-4.4694	-3.8826
TRTPN (ATPTN)	1	1	2	4	-6.0869	-5.1815
TRTPN (ATPTN)	1	1	1	5	-2.0876	-1.5009
TRTPN (ATPTN)	1	1	2	5	-2.9821	-2.0737
TRTPN (ATPTN)	1	1	1	6	-4.7257	-4.1384
TRTPN (ATPTN)	1	1	2	6	-5.9282	-5.0152
TRTPN (ATPTN)	1	1	1	7	-3.3703	-2.7791
TRTPN (ATPTN)	1	1	2	7	-4.6028	-3.6868
TRTPN (ATPTN)	1	1	1	8	-0.7352	-0.1434
TRTPN (ATPTN)	1	1	2	8	-1.6057	-0.6927
TRTPN (ATPTN)	1	1	1	9	-0.3157	0.2693
TRTPN (ATPTN)	1	1	2	9	-0.8743	0.02937
TRTPN (ATPTN)	2	1	1	2	-3.9430	-3.0410
TRTPN (ATPTN)	2	1	2	2	-5.1744	-4.3352
TRTPN (ATPTN)	2	1	1	3	-1.3569	-0.4552
TRTPN (ATPTN)	2	1	2	3	-2.6056	-1.7664
TRTPN (ATPTN)	2	1	1	4	-4.1171	-3.2153
TRTPN (ATPTN)	2	1	2	4	-5.5407	-4.7081
TRTPN (ATPTN)	2	1	1	5	-1.7353	-0.8336
TRTPN (ATPTN)	2	1	2	5	-2.4361	-1.6002
TRTPN (ATPTN)	2	1	1	6	-4.3733	-3.4712
TRTPN (ATPTN)	2	1	2	6	-5.3823	-4.5415
TRTPN (ATPTN)	2	1	1	7	-3.0172	-2.1126
TRTPN (ATPTN)	2	1	2	7	-4.0571	-3.2129
TRTPN (ATPTN)	2	1	1	8	-0.3820	0.5230
TRTPN (ATPTN)	2	1	2	8	-1.0599	-0.2189
TRTPN (ATPTN)	2	1	1	9	0.03632	0.9369
TRTPN (ATPTN)	2	1	2	9	-0.3280	0.5027
TRTPN (ATPTN)	1	2	2	2	-1.7193	-0.8065
TRTPN (ATPTN)	1	2	1	3	2.2916	2.8803
TRTPN (ATPTN)	1	2	2	3	0.8495	1.7624
TRTPN (ATPTN)	1	2	1	4	-0.4686	0.1201
TRTPN (ATPTN)	1	2	2	4	-2.0858	-1.1790
TRTPN (ATPTN)	1	2	1	5	1.9131	2.5018
TRTPN (ATPTN)	1	2	2	5	1.0189	1.9288
TRTPN (ATPTN)	1	2	1	6	-0.7250	-0.1357
TRTPN (ATPTN)	1	2	2	6	-1.9271	-1.0127
TRTPN (ATPTN)	1	2	1	7	0.6305	1.2237
TRTPN (ATPTN)	1	2	2	7	-0.6018	0.3157
TRTPN (ATPTN)	1	2	1	8	3.2656	3.8593
TRTPN (ATPTN)	1	2	2	8	2.3953	3.3098
TRTPN (ATPTN)	1	2	1	9	3.6849	4.2722
TRTPN (ATPTN)	1	2	2	9	3.1268	4.0318

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)	2	2	1	3	3.3925	4.3051
TRTPN (ATPTN)	2	2	2	3	2.1447	2.9930
TRTPN (ATPTN)	2	2	1	4	0.6323	1.5449
TRTPN (ATPTN)	2	2	2	4	-0.7906	0.05156
TRTPN (ATPTN)	2	2	1	5	3.0141	3.9266
TRTPN (ATPTN)	2	2	2	5	2.3140	3.1594
TRTPN (ATPTN)	2	2	1	6	0.3761	1.2890
TRTPN (ATPTN)	2	2	2	6	-0.6318	0.2177
TRTPN (ATPTN)	2	2	1	7	1.7322	2.6477
TRTPN (ATPTN)	2	2	2	7	0.6934	1.5462
TRTPN (ATPTN)	2	2	1	8	4.3674	5.2832
TRTPN (ATPTN)	2	2	2	8	3.6905	4.5404
TRTPN (ATPTN)	2	2	1	9	4.7857	5.6972
TRTPN (ATPTN)	2	2	2	9	4.4214	5.2630
TRTPN (ATPTN)	1	3	2	3	-1.7362	-0.8237
TRTPN (ATPTN)	1	3	1	4	-3.0542	-2.4662
TRTPN (ATPTN)	1	3	2	4	-4.6716	-3.7651
TRTPN (ATPTN)	1	3	1	5	-0.6725	-0.08446
TRTPN (ATPTN)	1	3	2	5	-1.5669	-0.6573
TRTPN (ATPTN)	1	3	1	6	-3.3106	-2.7220
TRTPN (ATPTN)	1	3	2	6	-4.5129	-3.5989
TRTPN (ATPTN)	1	3	1	7	-1.9551	-1.3627
TRTPN (ATPTN)	1	3	2	7	-3.1876	-2.2704
TRTPN (ATPTN)	1	3	1	8	0.6800	1.2730
TRTPN (ATPTN)	1	3	2	8	-0.1905	0.7237
TRTPN (ATPTN)	1	3	1	9	1.0992	1.6860
TRTPN (ATPTN)	1	3	2	9	0.5410	1.4457
TRTPN (ATPTN)	2	3	1	4	-1.9365	-1.0239
TRTPN (ATPTN)	2	3	2	4	-3.3597	-2.5170
TRTPN (ATPTN)	2	3	1	5	0.4452	1.3578
TRTPN (ATPTN)	2	3	2	5	-0.2544	0.5901
TRTPN (ATPTN)	2	3	1	6	-2.1927	-1.2798
TRTPN (ATPTN)	2	3	2	6	-3.2009	-2.3510
TRTPN (ATPTN)	2	3	1	7	-0.8366	0.07881
TRTPN (ATPTN)	2	3	2	7	-1.8756	-1.0224
TRTPN (ATPTN)	2	3	1	8	1.7986	2.7144
TRTPN (ATPTN)	2	3	2	8	1.1220	1.9712
TRTPN (ATPTN)	2	3	1	9	2.2169	3.1283
TRTPN (ATPTN)	2	3	2	9	1.8525	2.6941
TRTPN (ATPTN)	1	4	2	4	-1.9114	-1.0049
TRTPN (ATPTN)	1	4	1	5	2.0877	2.6757
TRTPN (ATPTN)	1	4	2	5	1.1933	2.1029
TRTPN (ATPTN)	1	4	1	6	-0.5503	0.03819
TRTPN (ATPTN)	1	4	2	6	-1.7527	-0.8386
TRTPN (ATPTN)	1	4	1	7	0.8051	1.3976
TRTPN (ATPTN)	1	4	2	7	-0.4274	0.4898
TRTPN (ATPTN)	1	4	1	8	3.4402	4.0332
TRTPN (ATPTN)	1	4	2	8	2.5697	3.4839
TRTPN (ATPTN)	1	4	1	9	3.8594	4.4462
TRTPN (ATPTN)	1	4	2	9	3.3011	4.2059
TRTPN (ATPTN)	2	4	1	5	3.3866	4.2931
TRTPN (ATPTN)	2	4	2	5	2.6865	3.5260
TRTPN (ATPTN)	2	4	1	6	0.7487	1.6555
TRTPN (ATPTN)	2	4	2	6	-0.2594	0.5844
TRTPN (ATPTN)	2	4	1	7	2.1048	3.0142
TRTPN (ATPTN)	2	4	2	7	1.0658	1.9129
TRTPN (ATPTN)	2	4	1	8	4.7400	5.6497
TRTPN (ATPTN)	2	4	2	8	4.0630	4.9069
TRTPN (ATPTN)	2	4	1	9	5.1583	6.0637

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)	2	4	2	9	4.7942	5.6292
TRTPN (ATPTN)	1	5	2	5	-1.1884	-0.2789
TRTPN (ATPTN)	1	5	1	6	-2.9321	-2.3435
TRTPN (ATPTN)	1	5	2	6	-4.1345	-3.2204
TRTPN (ATPTN)	1	5	1	7	-1.5766	-0.9842
TRTPN (ATPTN)	1	5	2	7	-2.8091	-1.8920
TRTPN (ATPTN)	1	5	1	8	1.0585	1.6514
TRTPN (ATPTN)	1	5	2	8	0.1880	1.1021
TRTPN (ATPTN)	1	5	1	9	1.4777	2.0645
TRTPN (ATPTN)	1	5	2	9	0.9194	1.8242
TRTPN (ATPTN)	2	5	1	6	-2.3591	-1.4492
TRTPN (ATPTN)	2	5	2	6	-3.3671	-2.5205
TRTPN (ATPTN)	2	5	1	7	-1.0030	-0.09055
TRTPN (ATPTN)	2	5	2	7	-2.0419	-1.1919
TRTPN (ATPTN)	2	5	1	8	1.6322	2.5450
TRTPN (ATPTN)	2	5	2	8	0.9556	1.8018
TRTPN (ATPTN)	2	5	1	9	2.0505	2.9589
TRTPN (ATPTN)	2	5	2	9	1.6863	2.5246
TRTPN (ATPTN)	1	6	2	6	-1.4969	-0.5824
TRTPN (ATPTN)	1	6	1	7	1.0609	1.6539
TRTPN (ATPTN)	1	6	2	7	-0.1715	0.7460
TRTPN (ATPTN)	1	6	1	8	3.6960	4.2896
TRTPN (ATPTN)	1	6	2	8	2.8256	3.7401
TRTPN (ATPTN)	1	6	1	9	4.1152	4.7025
TRTPN (ATPTN)	1	6	2	9	3.5570	4.4622
TRTPN (ATPTN)	2	6	1	7	1.9385	2.8555
TRTPN (ATPTN)	2	6	2	7	0.8995	1.7543
TRTPN (ATPTN)	2	6	1	8	4.5737	5.4911
TRTPN (ATPTN)	2	6	2	8	3.8969	4.7480
TRTPN (ATPTN)	2	6	1	9	4.9920	5.9050
TRTPN (ATPTN)	2	6	2	9	4.6276	5.4709
TRTPN (ATPTN)	1	7	2	7	-1.5301	-0.6101
TRTPN (ATPTN)	1	7	1	8	2.3368	2.9339
TRTPN (ATPTN)	1	7	2	8	1.4670	2.3840
TRTPN (ATPTN)	1	7	1	9	2.7559	3.3471
TRTPN (ATPTN)	1	7	2	9	2.1984	3.1061
TRTPN (ATPTN)	2	7	1	8	3.2453	4.1657
TRTPN (ATPTN)	2	7	2	8	2.5684	3.4228
TRTPN (ATPTN)	2	7	1	9	3.6636	4.5796
TRTPN (ATPTN)	2	7	2	9	3.2991	4.1457
TRTPN (ATPTN)	1	8	2	8	-1.1686	-0.2512
TRTPN (ATPTN)	1	8	1	9	0.1202	0.7120
TRTPN (ATPTN)	1	8	2	9	-0.4372	0.4709
TRTPN (ATPTN)	2	8	1	9	0.6695	1.5825
TRTPN (ATPTN)	2	8	2	9	0.3051	1.1484
TRTPN (ATPTN)	1	9	2	9	-0.8511	0.05258

NN9068
NN9068-4166
Clinical Trial Report
Statistical document

~~CONFIDENTIAL~~

Date:	22 January 2020	Novo Nordisk
Version:	1.0	
Status:	Final	
Page:	183 of 334	

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

Class Level Information

Class	Levels	Values
USUBJID	453	



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure



9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure



TRTPN 2 1 2
ATPTN 9 1 2 3 4 5 6 7 8 9
PREAD 2 BASAL INSULIN + METFORMIN
BASAL INSULIN + METFORMIN +
ONE OTHER OAD

Dimensions

Covariance Parameters 2
Columns in X 39
Columns in Z 0

9-point self-measured plasma glucose profile after 26 weeks of treatment - supportive statistical analysis - full analysis set

Parameter Code=SMPGCOL

The Mixed Procedure

Dimensions

Subjects 453
 Max Obs per Subject 9

Number of Observations

Number of Observations Read 4077
 Number of Observations Used 3987
 Number of Observations Not Used 90

Iteration History

Iteration	Evaluations	-2 Res Log Like	Criterion
0	1	40881.40823158	
1	2	39887.00950934	0.00000000

Convergence criteria met.

Covariance Parameter Estimates

Cov Parm	Subject	Estimate	Standard Error	Z Value	Pr > Z	Alpha	Lower	Upper
CS	USUBJID	631.46	50.5711	12.49	<.0001	0.05	532.34	730.57
Residual		1091.10	26.0426	41.90	<.0001	0.05	1041.80	1143.99

Asymptotic Covariance Matrix of Estimates

Row	Cov Parm	CovP1	CovP2
1	CS	2557.44	-77.8457
2	Residual	-77.8457	678.22

Fit Statistics

-2 Res Log Likelihood 39887.0
 AIC (Smaller is Better) 39891.0
 AICC (Smaller is Better) 39891.0
 BIC (Smaller is Better) 39899.2

Null Model Likelihood Ratio Test

DF	Chi-Square	Pr > ChiSq
1	994.40	<.0001

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Analysis Timepoint (N)	Estimate	Standard Error
Intercept		01 (N)		107.76	3.8891
TRTPN		1		-7.1946	4.1516
TRTPN		2		0	

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 treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Estimate	Standard Error
TRTPN (ATPTN)		1	1	0.7033	3.3840
TRTPN (ATPTN)		2	1	2.6952	4.3757
TRTPN (ATPTN)		1	2	71.8421	3.4058
TRTPN (ATPTN)		2	2	87.4046	4.3979
TRTPN (ATPTN)		1	3	22.0372	3.4006
TRTPN (ATPTN)		2	3	37.9077	4.4057
TRTPN (ATPTN)		1	4	72.8432	3.3924
TRTPN (ATPTN)		2	4	91.9248	4.3856
TRTPN (ATPTN)		1	5	33.1905	3.3989
TRTPN (ATPTN)		2	5	39.2162	4.3997
TRTPN (ATPTN)		1	6	80.0601	3.3967
TRTPN (ATPTN)		2	6	91.5997	4.4173
TRTPN (ATPTN)		1	7	54.3426	3.4347
TRTPN (ATPTN)		2	7	66.4318	4.4361
TRTPN (ATPTN)		1	8	7.8283	3.4334
TRTPN (ATPTN)		2	8	13.4264	4.4143
TRTPN (ATPTN)		1	9	0	
TRTPN (ATPTN)		2	9	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		1	-2.7250	3.9060
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		1	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		2	-0.6754	3.9435
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		2	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		3	6.0799	3.9403
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		3	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		4	3.8311	3.9276
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		4	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		5	-3.0503	3.9334
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		5	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		6	-1.6527	3.9476
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		6	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		7	0.9968	3.9739
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		7	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		8	-1.0581	3.9719
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		8	0	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		9	-0.3624	3.9131
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		9	0	

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	DF	t Value
Intercept				1934	27.71
TRTPN		1		1940	-1.73
TRTPN		2			
TRTPN (ATPTN)		1	1	3512	0.21
TRTPN (ATPTN)		2	1	3513	0.62
TRTPN (ATPTN)		1	2	3516	21.09
TRTPN (ATPTN)		2	2	3514	19.87
TRTPN (ATPTN)		1	3	3515	6.48
TRTPN (ATPTN)		2	3	3516	8.60
TRTPN (ATPTN)		1	4	3514	21.47
TRTPN (ATPTN)		2	4	3513	20.96
TRTPN (ATPTN)		1	5	3515	9.77
TRTPN (ATPTN)		2	5	3515	8.91
TRTPN (ATPTN)		1	6	3515	23.57

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 treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	DF	t Value
TRTPN (ATPTN)		2	6	3516	20.74
TRTPN (ATPTN)		1	7	3518	15.82
TRTPN (ATPTN)		2	7	3517	14.98
TRTPN (ATPTN)		1	8	3518	2.28
TRTPN (ATPTN)		2	8	3516	3.04
TRTPN (ATPTN)		1	9		
TRTPN (ATPTN)		2	9		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		1	1927	-0.70
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		1		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		2	1970	-0.17
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		2		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		3	1965	1.54
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		3		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		4	1949	0.98
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		4		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		5	1956	-0.78
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		5		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		6	1975	-0.42
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		6		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		7	2009	0.25
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		7		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		8	2006	-0.27
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		8		
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		9	1934	-0.09
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		9		

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Pr > t
Intercept				<.0001
TRTPN		1		0.0833
TRTPN		2		
TRTPN (ATPTN)		1	1	0.8354
TRTPN (ATPTN)		2	1	0.5380
TRTPN (ATPTN)		1	2	<.0001
TRTPN (ATPTN)		2	2	<.0001
TRTPN (ATPTN)		1	3	<.0001
TRTPN (ATPTN)		2	3	<.0001
TRTPN (ATPTN)		1	4	<.0001
TRTPN (ATPTN)		2	4	<.0001
TRTPN (ATPTN)		1	5	<.0001
TRTPN (ATPTN)		2	5	<.0001
TRTPN (ATPTN)		1	6	<.0001
TRTPN (ATPTN)		2	6	<.0001
TRTPN (ATPTN)		1	7	<.0001
TRTPN (ATPTN)		2	7	<.0001
TRTPN (ATPTN)		1	8	0.0227
TRTPN (ATPTN)		2	8	0.0024
TRTPN (ATPTN)		1	9	
TRTPN (ATPTN)		2	9	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		1	0.4855
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		1	
PREAD (ATPTN)	BASAL INSULIN + METFORMIN		2	0.8640
PREAD (ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		2	

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 treatment	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Pr > t
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		3	0.1230
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		3	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		4	0.3295
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		4	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		5	0.4381
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		5	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		6	0.6755
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		6	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		7	0.8020
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		7	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		8	0.7900
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		8	
PREAD(ATPTN)	BASAL INSULIN + METFORMIN		9	0.9262
PREAD(ATPTN)	BASAL INSULIN + METFORMIN + ONE OTHER OAD		9	

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
TRTPN	1	451	38.01	<.0001
TRTPN(ATPTN)	8	3517	3.99	0.0001
PREAD(ATPTN)	9	3357	0.83	0.5889

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	99.9780	2.3885	1927	41.86	<.0001
TRTPN(ATPTN)	2	1	WORK.ANA_DATA	109.16	3.3781	1927	32.32	<.0001
TRTPN(ATPTN)	1	2	WORK.ANA_DATA	172.09	2.4000	1950	71.70	<.0001
TRTPN(ATPTN)	2	2	WORK.ANA_DATA	194.85	3.4392	2006	56.65	<.0001
TRTPN(ATPTN)	1	3	WORK.ANA_DATA	125.49	2.3975	1943	52.34	<.0001
TRTPN(ATPTN)	2	3	WORK.ANA_DATA	148.56	3.4392	2006	43.20	<.0001
TRTPN(ATPTN)	1	4	WORK.ANA_DATA	175.23	2.3976	1944	73.08	<.0001

Least Squares Means

Effect	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Alpha	Lower	Upper
TRTPN(ATPTN)	1	1	0.05	95.2938	104.66
TRTPN(ATPTN)	2	1	0.05	102.54	115.79
TRTPN(ATPTN)	1	2	0.05	167.38	176.80
TRTPN(ATPTN)	2	2	0.05	188.10	201.59
TRTPN(ATPTN)	1	3	0.05	120.79	130.19
TRTPN(ATPTN)	2	3	0.05	141.81	155.30
TRTPN(ATPTN)	1	4	0.05	170.53	179.93

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)	2	4	WORK.ANA_DATA	201.51	3.4051	1957	59.18	<.0001
TRTPN (ATPTN)	1	5	WORK.ANA_DATA	132.31	2.3975	1943	55.19	<.0001
TRTPN (ATPTN)	2	5	WORK.ANA_DATA	145.53	3.4223	1981	42.52	<.0001
TRTPN (ATPTN)	1	6	WORK.ANA_DATA	179.84	2.4005	1950	74.92	<.0001
TRTPN (ATPTN)	2	6	WORK.ANA_DATA	198.58	3.4477	2018	57.60	<.0001
TRTPN (ATPTN)	1	7	WORK.ANA_DATA	155.38	2.4205	1992	64.20	<.0001
TRTPN (ATPTN)	2	7	WORK.ANA_DATA	174.67	3.4650	2044	50.41	<.0001
TRTPN (ATPTN)	1	8	WORK.ANA_DATA	107.89	2.4234	1998	44.52	<.0001
TRTPN (ATPTN)	2	8	WORK.ANA_DATA	120.69	3.4481	2018	35.00	<.0001
TRTPN (ATPTN)	1	9	WORK.ANA_DATA	100.40	2.3885	1927	42.03	<.0001
TRTPN (ATPTN)	2	9	WORK.ANA_DATA	107.59	3.3954	1947	31.69	<.0001

Least Squares Means

Effect	Planned Treatment for Period 01 (N)	Analysis Timepoint (N)	Alpha	Lower	Upper
TRTPN (ATPTN)	2	4	0.05	194.83	208.18
TRTPN (ATPTN)	1	5	0.05	127.61	137.01
TRTPN (ATPTN)	2	5	0.05	138.82	152.24
TRTPN (ATPTN)	1	6	0.05	175.14	184.55
TRTPN (ATPTN)	2	6	0.05	191.82	205.34
TRTPN (ATPTN)	1	7	0.05	150.64	160.13
TRTPN (ATPTN)	2	7	0.05	167.87	181.46
TRTPN (ATPTN)	1	8	0.05	103.14	112.65
TRTPN (ATPTN)	2	8	0.05	113.92	127.45
TRTPN (ATPTN)	1	9	0.05	95.7118	105.08
TRTPN (ATPTN)	2	9	0.05	100.93	114.25

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	-9.1865	4.1376	1927
TRTPN (ATPTN)	1	1	1	2	WORK.ANA_DATA	-72.1116	2.6986	3513
TRTPN (ATPTN)	1	1	2	2	WORK.ANA_DATA	-94.8687	4.1874	1979
TRTPN (ATPTN)	1	1	1	3	WORK.ANA_DATA	-25.5128	2.6963	3514
TRTPN (ATPTN)	1	1	2	3	WORK.ANA_DATA	-48.5780	4.1874	1979
TRTPN (ATPTN)	1	1	1	4	WORK.ANA_DATA	-75.2515	2.6964	3514
TRTPN (ATPTN)	1	1	2	4	WORK.ANA_DATA	-101.53	4.1594	1947
TRTPN (ATPTN)	1	1	1	5	WORK.ANA_DATA	-32.3329	2.6964	3514
TRTPN (ATPTN)	1	1	2	5	WORK.ANA_DATA	-45.5531	4.1735	1963
TRTPN (ATPTN)	1	1	1	6	WORK.ANA_DATA	-79.8657	2.6990	3514
TRTPN (ATPTN)	1	1	2	6	WORK.ANA_DATA	-98.6000	4.1944	1988
TRTPN (ATPTN)	1	1	1	7	WORK.ANA_DATA	-55.4058	2.7168	3516
TRTPN (ATPTN)	1	1	2	7	WORK.ANA_DATA	-74.6896	4.2086	2005
TRTPN (ATPTN)	1	1	1	8	WORK.ANA_DATA	-7.9162	2.7194	3516
TRTPN (ATPTN)	1	1	2	8	WORK.ANA_DATA	-20.7089	4.1947	1988
TRTPN (ATPTN)	1	1	1	9	WORK.ANA_DATA	-0.4180	2.6883	3511
TRTPN (ATPTN)	1	1	2	9	WORK.ANA_DATA	-7.6126	4.1515	1940
TRTPN (ATPTN)	2	1	1	2	WORK.ANA_DATA	-62.9251	4.1440	1934

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	1	2	2	WORK.ANA_DATA	-85.6821	3.8566	3526
TRTPN (ATPTN)	2	1	1	3	WORK.ANA_DATA	-16.3263	4.1425	1932
TRTPN (ATPTN)	2	1	2	3	WORK.ANA_DATA	-39.3915	3.8565	3526
TRTPN (ATPTN)	2	1	1	4	WORK.ANA_DATA	-66.0650	4.1426	1932
TRTPN (ATPTN)	2	1	2	4	WORK.ANA_DATA	-92.3412	3.8262	3522
TRTPN (ATPTN)	2	1	1	5	WORK.ANA_DATA	-23.1463	4.1426	1932
TRTPN (ATPTN)	2	1	2	5	WORK.ANA_DATA	-36.3666	3.8415	3525
TRTPN (ATPTN)	2	1	1	6	WORK.ANA_DATA	-70.6792	4.1443	1934
TRTPN (ATPTN)	2	1	2	6	WORK.ANA_DATA	-89.4134	3.8642	3527
TRTPN (ATPTN)	2	1	1	7	WORK.ANA_DATA	-46.2192	4.1559	1948
TRTPN (ATPTN)	2	1	2	7	WORK.ANA_DATA	-65.5031	3.8796	3528
TRTPN (ATPTN)	2	1	1	8	WORK.ANA_DATA	1.2704	4.1576	1950
TRTPN (ATPTN)	2	1	2	8	WORK.ANA_DATA	-11.5224	3.8645	3527
TRTPN (ATPTN)	2	1	1	9	WORK.ANA_DATA	8.7685	4.1373	1926
TRTPN (ATPTN)	2	1	2	9	WORK.ANA_DATA	1.5739	3.8176	3517
TRTPN (ATPTN)	1	2	2	2	WORK.ANA_DATA	-22.7570	4.1938	1987
TRTPN (ATPTN)	1	2	1	3	WORK.ANA_DATA	46.5988	2.7054	3513
TRTPN (ATPTN)	1	2	2	3	WORK.ANA_DATA	23.5336	4.1939	1987
TRTPN (ATPTN)	1	2	1	4	WORK.ANA_DATA	-3.1399	2.7055	3513
TRTPN (ATPTN)	1	2	2	4	WORK.ANA_DATA	-29.4161	4.1660	1954
TRTPN (ATPTN)	1	2	1	5	WORK.ANA_DATA	39.7788	2.7054	3513
TRTPN (ATPTN)	1	2	2	5	WORK.ANA_DATA	26.5585	4.1801	1970
TRTPN (ATPTN)	1	2	1	6	WORK.ANA_DATA	-7.7541	2.7081	3513
TRTPN (ATPTN)	1	2	2	6	WORK.ANA_DATA	-26.4884	4.2009	1995
TRTPN (ATPTN)	1	2	1	7	WORK.ANA_DATA	16.7059	2.7258	3515
TRTPN (ATPTN)	1	2	2	7	WORK.ANA_DATA	-2.5780	4.2151	2013
TRTPN (ATPTN)	1	2	1	8	WORK.ANA_DATA	64.1955	2.7279	3515
TRTPN (ATPTN)	1	2	2	8	WORK.ANA_DATA	51.4027	4.2012	1995
TRTPN (ATPTN)	1	2	1	9	WORK.ANA_DATA	71.6936	2.6986	3513
TRTPN (ATPTN)	1	2	2	9	WORK.ANA_DATA	64.4990	4.1581	1947
TRTPN (ATPTN)	2	2	1	3	WORK.ANA_DATA	69.3559	4.1925	1985
TRTPN (ATPTN)	2	2	2	3	WORK.ANA_DATA	46.2907	3.8985	3516
TRTPN (ATPTN)	2	2	1	4	WORK.ANA_DATA	19.6172	4.1926	1985
TRTPN (ATPTN)	2	2	2	4	WORK.ANA_DATA	-6.6591	3.8703	3515
TRTPN (ATPTN)	2	2	1	5	WORK.ANA_DATA	62.5358	4.1925	1985
TRTPN (ATPTN)	2	2	2	5	WORK.ANA_DATA	49.3156	3.8851	3516
TRTPN (ATPTN)	2	2	1	6	WORK.ANA_DATA	15.0029	4.1943	1987
TRTPN (ATPTN)	2	2	2	6	WORK.ANA_DATA	-3.7313	3.9037	3514
TRTPN (ATPTN)	2	2	1	7	WORK.ANA_DATA	39.4629	4.2057	2001
TRTPN (ATPTN)	2	2	2	7	WORK.ANA_DATA	20.1791	3.9190	3515
TRTPN (ATPTN)	2	2	1	8	WORK.ANA_DATA	86.9525	4.2074	2003
TRTPN (ATPTN)	2	2	2	8	WORK.ANA_DATA	74.1598	3.9057	3516
TRTPN (ATPTN)	2	2	1	9	WORK.ANA_DATA	94.4506	4.1874	1979
TRTPN (ATPTN)	2	2	2	9	WORK.ANA_DATA	87.2560	3.8675	3520
TRTPN (ATPTN)	1	3	2	3	WORK.ANA_DATA	-23.0652	4.1924	1985
TRTPN (ATPTN)	1	3	1	4	WORK.ANA_DATA	-49.7387	2.7023	3511
TRTPN (ATPTN)	1	3	2	4	WORK.ANA_DATA	-76.0149	4.1646	1952
TRTPN (ATPTN)	1	3	1	5	WORK.ANA_DATA	-6.8201	2.7022	3511
TRTPN (ATPTN)	1	3	2	5	WORK.ANA_DATA	-20.0403	4.1787	1968
TRTPN (ATPTN)	1	3	1	6	WORK.ANA_DATA	-54.3530	2.7049	3512
TRTPN (ATPTN)	1	3	2	6	WORK.ANA_DATA	-73.0872	4.1995	1993
TRTPN (ATPTN)	1	3	1	7	WORK.ANA_DATA	-29.8930	2.7221	3513
TRTPN (ATPTN)	1	3	2	7	WORK.ANA_DATA	-49.1768	4.2137	2011
TRTPN (ATPTN)	1	3	1	8	WORK.ANA_DATA	17.5966	2.7253	3514
TRTPN (ATPTN)	1	3	2	8	WORK.ANA_DATA	4.8039	4.1998	1993
TRTPN (ATPTN)	1	3	1	9	WORK.ANA_DATA	25.0948	2.6963	3514
TRTPN (ATPTN)	1	3	2	9	WORK.ANA_DATA	17.9001	4.1567	1945
TRTPN (ATPTN)	2	3	1	4	WORK.ANA_DATA	-26.6735	4.1926	1985
TRTPN (ATPTN)	2	3	2	4	WORK.ANA_DATA	-52.9497	3.8725	3518

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	3	1	5	WORK.ANA_DATA	16.2451	4.1925	1985
TRTPN (ATPTN)	2	3	2	5	WORK.ANA_DATA	3.0249	3.8810	3512
TRTPN (ATPTN)	2	3	1	6	WORK.ANA_DATA	-31.2878	4.1942	1987
TRTPN (ATPTN)	2	3	2	6	WORK.ANA_DATA	-50.0220	3.9056	3516
TRTPN (ATPTN)	2	3	1	7	WORK.ANA_DATA	-6.8278	4.2056	2001
TRTPN (ATPTN)	2	3	2	7	WORK.ANA_DATA	-26.1116	3.9209	3518
TRTPN (ATPTN)	2	3	1	8	WORK.ANA_DATA	40.6618	4.2074	2003
TRTPN (ATPTN)	2	3	2	8	WORK.ANA_DATA	27.8691	3.9024	3513
TRTPN (ATPTN)	2	3	1	9	WORK.ANA_DATA	48.1600	4.1873	1979
TRTPN (ATPTN)	2	3	2	9	WORK.ANA_DATA	40.9653	3.8674	3520
TRTPN (ATPTN)	1	4	2	4	WORK.ANA_DATA	-26.2762	4.1647	1952
TRTPN (ATPTN)	1	4	1	5	WORK.ANA_DATA	42.9186	2.7023	3511
TRTPN (ATPTN)	1	4	2	5	WORK.ANA_DATA	29.6984	4.1788	1968
TRTPN (ATPTN)	1	4	1	6	WORK.ANA_DATA	-4.6142	2.7045	3511
TRTPN (ATPTN)	1	4	2	6	WORK.ANA_DATA	-23.3485	4.1996	1993
TRTPN (ATPTN)	1	4	1	7	WORK.ANA_DATA	19.8457	2.7227	3514
TRTPN (ATPTN)	1	4	2	7	WORK.ANA_DATA	0.5619	4.2138	2011
TRTPN (ATPTN)	1	4	1	8	WORK.ANA_DATA	67.3353	2.7254	3514
TRTPN (ATPTN)	1	4	2	8	WORK.ANA_DATA	54.5426	4.1999	1993
TRTPN (ATPTN)	1	4	1	9	WORK.ANA_DATA	74.8335	2.6964	3514
TRTPN (ATPTN)	1	4	2	9	WORK.ANA_DATA	67.6388	4.1568	1945
TRTPN (ATPTN)	2	4	1	5	WORK.ANA_DATA	69.1949	4.1646	1952
TRTPN (ATPTN)	2	4	2	5	WORK.ANA_DATA	55.9746	3.8575	3517
TRTPN (ATPTN)	2	4	1	6	WORK.ANA_DATA	21.6620	4.1663	1954
TRTPN (ATPTN)	2	4	2	6	WORK.ANA_DATA	2.9278	3.8778	3516
TRTPN (ATPTN)	2	4	1	7	WORK.ANA_DATA	46.1220	4.1778	1968
TRTPN (ATPTN)	2	4	2	7	WORK.ANA_DATA	26.8381	3.8932	3517
TRTPN (ATPTN)	2	4	1	8	WORK.ANA_DATA	93.6116	4.1796	1970
TRTPN (ATPTN)	2	4	2	8	WORK.ANA_DATA	80.8188	3.8782	3516
TRTPN (ATPTN)	2	4	1	9	WORK.ANA_DATA	101.11	4.1594	1947
TRTPN (ATPTN)	2	4	2	9	WORK.ANA_DATA	93.9151	3.8371	3516
TRTPN (ATPTN)	1	5	2	5	WORK.ANA_DATA	-13.2203	4.1788	1968
TRTPN (ATPTN)	1	5	1	6	WORK.ANA_DATA	-47.5329	2.7049	3512
TRTPN (ATPTN)	1	5	2	6	WORK.ANA_DATA	-66.2671	4.1995	1993
TRTPN (ATPTN)	1	5	1	7	WORK.ANA_DATA	-23.0729	2.7221	3513
TRTPN (ATPTN)	1	5	2	7	WORK.ANA_DATA	-42.3568	4.2137	2011
TRTPN (ATPTN)	1	5	1	8	WORK.ANA_DATA	24.4167	2.7247	3513
TRTPN (ATPTN)	1	5	2	8	WORK.ANA_DATA	11.6240	4.1998	1993
TRTPN (ATPTN)	1	5	1	9	WORK.ANA_DATA	31.9148	2.6964	3514
TRTPN (ATPTN)	1	5	2	9	WORK.ANA_DATA	24.7202	4.1567	1945
TRTPN (ATPTN)	2	5	1	6	WORK.ANA_DATA	-34.3126	4.1804	1970
TRTPN (ATPTN)	2	5	2	6	WORK.ANA_DATA	-53.0469	3.8907	3515
TRTPN (ATPTN)	2	5	1	7	WORK.ANA_DATA	-9.8526	4.1919	1984
TRTPN (ATPTN)	2	5	2	7	WORK.ANA_DATA	-29.1365	3.9060	3516
TRTPN (ATPTN)	2	5	1	8	WORK.ANA_DATA	37.6369	4.1936	1986
TRTPN (ATPTN)	2	5	2	8	WORK.ANA_DATA	24.8442	3.8890	3513
TRTPN (ATPTN)	2	5	1	9	WORK.ANA_DATA	45.1351	4.1735	1963
TRTPN (ATPTN)	2	5	2	9	WORK.ANA_DATA	37.9405	3.8524	3519
TRTPN (ATPTN)	1	6	2	6	WORK.ANA_DATA	-18.7342	4.2012	1995
TRTPN (ATPTN)	1	6	1	7	WORK.ANA_DATA	24.4600	2.7253	3514
TRTPN (ATPTN)	1	6	2	7	WORK.ANA_DATA	5.1761	4.2154	2013
TRTPN (ATPTN)	1	6	1	8	WORK.ANA_DATA	71.9496	2.7279	3514
TRTPN (ATPTN)	1	6	2	8	WORK.ANA_DATA	59.1568	4.2015	1995
TRTPN (ATPTN)	1	6	1	9	WORK.ANA_DATA	79.4477	2.6990	3514
TRTPN (ATPTN)	1	6	2	9	WORK.ANA_DATA	72.2531	4.1584	1947
TRTPN (ATPTN)	2	6	1	7	WORK.ANA_DATA	43.1942	4.2127	2009
TRTPN (ATPTN)	2	6	2	7	WORK.ANA_DATA	23.9104	3.9282	3518
TRTPN (ATPTN)	2	6	1	8	WORK.ANA_DATA	90.6838	4.2144	2011
TRTPN (ATPTN)	2	6	2	8	WORK.ANA_DATA	77.8911	3.9112	3515

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)	Margins	Estimate	Standard Error	DF
TRTPN (ATPTN)	2	6	1	9	WORK.ANA_DATA	98.1819	4.1944	1988
TRTPN (ATPTN)	2	6	2	9	WORK.ANA_DATA	90.9873	3.8750	3521
TRTPN (ATPTN)	1	7	2	7	WORK.ANA_DATA	-19.2838	4.2268	2026
TRTPN (ATPTN)	1	7	1	8	WORK.ANA_DATA	47.4896	2.7440	3514
TRTPN (ATPTN)	1	7	2	8	WORK.ANA_DATA	34.6969	4.2130	2009
TRTPN (ATPTN)	1	7	1	9	WORK.ANA_DATA	54.9877	2.7168	3516
TRTPN (ATPTN)	1	7	2	9	WORK.ANA_DATA	47.7931	4.1700	1961
TRTPN (ATPTN)	2	7	1	8	WORK.ANA_DATA	66.7734	4.2285	2029
TRTPN (ATPTN)	2	7	2	8	WORK.ANA_DATA	53.9807	3.9265	3516
TRTPN (ATPTN)	2	7	1	9	WORK.ANA_DATA	74.2716	4.2086	2005
TRTPN (ATPTN)	2	7	2	9	WORK.ANA_DATA	67.0770	3.8904	3522
TRTPN (ATPTN)	1	8	2	8	WORK.ANA_DATA	-12.7927	4.2147	2011
TRTPN (ATPTN)	1	8	1	9	WORK.ANA_DATA	7.4981	2.7194	3516
TRTPN (ATPTN)	1	8	2	9	WORK.ANA_DATA	0.3035	4.1717	1964
TRTPN (ATPTN)	2	8	1	9	WORK.ANA_DATA	20.2909	4.1947	1988
TRTPN (ATPTN)	2	8	2	9	WORK.ANA_DATA	13.0962	3.8754	3522
TRTPN (ATPTN)	1	9	2	9	WORK.ANA_DATA	-7.1946	4.1516	1940

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	-2.22	0.0265	0.05
TRTPN (ATPTN)	1	1	1	2	-26.72	<.0001	0.05
TRTPN (ATPTN)	1	1	2	2	-22.66	<.0001	0.05
TRTPN (ATPTN)	1	1	1	3	-9.46	<.0001	0.05
TRTPN (ATPTN)	1	1	2	3	-11.60	<.0001	0.05
TRTPN (ATPTN)	1	1	1	4	-27.91	<.0001	0.05
TRTPN (ATPTN)	1	1	2	4	-24.41	<.0001	0.05
TRTPN (ATPTN)	1	1	1	5	-11.99	<.0001	0.05
TRTPN (ATPTN)	1	1	2	5	-10.91	<.0001	0.05
TRTPN (ATPTN)	1	1	1	6	-29.59	<.0001	0.05
TRTPN (ATPTN)	1	1	2	6	-23.51	<.0001	0.05
TRTPN (ATPTN)	1	1	1	7	-20.39	<.0001	0.05
TRTPN (ATPTN)	1	1	2	7	-17.75	<.0001	0.05
TRTPN (ATPTN)	1	1	1	8	-2.91	0.0036	0.05
TRTPN (ATPTN)	1	1	2	8	-4.94	<.0001	0.05
TRTPN (ATPTN)	1	1	1	9	-0.16	0.8764	0.05
TRTPN (ATPTN)	1	1	2	9	-1.83	0.0669	0.05
TRTPN (ATPTN)	2	1	1	2	-15.18	<.0001	0.05
TRTPN (ATPTN)	2	1	2	2	-22.22	<.0001	0.05
TRTPN (ATPTN)	2	1	1	3	-3.94	<.0001	0.05
TRTPN (ATPTN)	2	1	2	3	-10.21	<.0001	0.05
TRTPN (ATPTN)	2	1	1	4	-15.95	<.0001	0.05
TRTPN (ATPTN)	2	1	2	4	-24.13	<.0001	0.05
TRTPN (ATPTN)	2	1	1	5	-5.59	<.0001	0.05
TRTPN (ATPTN)	2	1	2	5	-9.47	<.0001	0.05
TRTPN (ATPTN)	2	1	1	6	-17.05	<.0001	0.05
TRTPN (ATPTN)	2	1	2	6	-23.14	<.0001	0.05
TRTPN (ATPTN)	2	1	1	7	-11.12	<.0001	0.05
TRTPN (ATPTN)	2	1	2	7	-16.88	<.0001	0.05
TRTPN (ATPTN)	2	1	1	8	0.31	0.7600	0.05
TRTPN (ATPTN)	2	1	2	8	-2.98	0.0029	0.05
TRTPN (ATPTN)	2	1	1	9	2.12	0.0342	0.05
TRTPN (ATPTN)	2	1	2	9	0.41	0.6802	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)	1	2	2	2	-5.43	<.0001	0.05
TRTPN (ATPTN)	1	2	1	3	17.22	<.0001	0.05
TRTPN (ATPTN)	1	2	2	3	5.61	<.0001	0.05
TRTPN (ATPTN)	1	2	1	4	-1.16	0.2459	0.05
TRTPN (ATPTN)	1	2	2	4	-7.06	<.0001	0.05
TRTPN (ATPTN)	1	2	1	5	14.70	<.0001	0.05
TRTPN (ATPTN)	1	2	2	5	6.35	<.0001	0.05
TRTPN (ATPTN)	1	2	1	6	-2.86	0.0042	0.05
TRTPN (ATPTN)	1	2	2	6	-6.31	<.0001	0.05
TRTPN (ATPTN)	1	2	1	7	6.13	<.0001	0.05
TRTPN (ATPTN)	1	2	2	7	-0.61	0.5409	0.05
TRTPN (ATPTN)	1	2	1	8	23.53	<.0001	0.05
TRTPN (ATPTN)	1	2	2	8	12.24	<.0001	0.05
TRTPN (ATPTN)	1	2	1	9	26.57	<.0001	0.05
TRTPN (ATPTN)	1	2	2	9	15.51	<.0001	0.05
TRTPN (ATPTN)	2	2	1	3	16.54	<.0001	0.05
TRTPN (ATPTN)	2	2	2	3	11.87	<.0001	0.05
TRTPN (ATPTN)	2	2	1	4	4.68	<.0001	0.05
TRTPN (ATPTN)	2	2	2	4	-1.72	0.0854	0.05
TRTPN (ATPTN)	2	2	1	5	14.92	<.0001	0.05
TRTPN (ATPTN)	2	2	2	5	12.69	<.0001	0.05
TRTPN (ATPTN)	2	2	1	6	3.58	0.0004	0.05
TRTPN (ATPTN)	2	2	2	6	-0.96	0.3392	0.05
TRTPN (ATPTN)	2	2	1	7	9.38	<.0001	0.05
TRTPN (ATPTN)	2	2	2	7	5.15	<.0001	0.05
TRTPN (ATPTN)	2	2	1	8	20.67	<.0001	0.05
TRTPN (ATPTN)	2	2	2	8	18.99	<.0001	0.05
TRTPN (ATPTN)	2	2	1	9	22.56	<.0001	0.05
TRTPN (ATPTN)	2	2	2	9	22.56	<.0001	0.05
TRTPN (ATPTN)	1	3	2	3	-5.50	<.0001	0.05
TRTPN (ATPTN)	1	3	1	4	-18.41	<.0001	0.05
TRTPN (ATPTN)	1	3	2	4	-18.25	<.0001	0.05
TRTPN (ATPTN)	1	3	1	5	-2.52	0.0117	0.05
TRTPN (ATPTN)	1	3	2	5	-4.80	<.0001	0.05
TRTPN (ATPTN)	1	3	1	6	-20.09	<.0001	0.05
TRTPN (ATPTN)	1	3	2	6	-17.40	<.0001	0.05
TRTPN (ATPTN)	1	3	1	7	-10.98	<.0001	0.05
TRTPN (ATPTN)	1	3	2	7	-11.67	<.0001	0.05
TRTPN (ATPTN)	1	3	1	8	6.46	<.0001	0.05
TRTPN (ATPTN)	1	3	2	8	1.14	0.2528	0.05
TRTPN (ATPTN)	1	3	1	9	9.31	<.0001	0.05
TRTPN (ATPTN)	1	3	2	9	4.31	<.0001	0.05
TRTPN (ATPTN)	2	3	1	4	-6.36	<.0001	0.05
TRTPN (ATPTN)	2	3	2	4	-13.67	<.0001	0.05
TRTPN (ATPTN)	2	3	1	5	3.87	0.0001	0.05
TRTPN (ATPTN)	2	3	2	5	0.78	0.4358	0.05
TRTPN (ATPTN)	2	3	1	6	-7.46	<.0001	0.05
TRTPN (ATPTN)	2	3	2	6	-12.81	<.0001	0.05
TRTPN (ATPTN)	2	3	1	7	-1.62	0.1046	0.05
TRTPN (ATPTN)	2	3	2	7	-6.66	<.0001	0.05
TRTPN (ATPTN)	2	3	1	8	9.66	<.0001	0.05
TRTPN (ATPTN)	2	3	2	8	7.14	<.0001	0.05
TRTPN (ATPTN)	2	3	1	9	11.50	<.0001	0.05
TRTPN (ATPTN)	2	3	2	9	10.59	<.0001	0.05
TRTPN (ATPTN)	1	4	2	4	-6.31	<.0001	0.05
TRTPN (ATPTN)	1	4	1	5	15.88	<.0001	0.05
TRTPN (ATPTN)	1	4	2	5	7.11	<.0001	0.05
TRTPN (ATPTN)	1	4	1	6	-1.71	0.0881	0.05
TRTPN (ATPTN)	1	4	2	6	-5.56	<.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)	1	4	1	7	7.29	<.0001	0.05
TRTPN (ATPTN)	1	4	2	7	0.13	0.8939	0.05
TRTPN (ATPTN)	1	4	1	8	24.71	<.0001	0.05
TRTPN (ATPTN)	1	4	2	8	12.99	<.0001	0.05
TRTPN (ATPTN)	1	4	1	9	27.75	<.0001	0.05
TRTPN (ATPTN)	1	4	2	9	16.27	<.0001	0.05
TRTPN (ATPTN)	2	4	1	5	16.62	<.0001	0.05
TRTPN (ATPTN)	2	4	2	5	14.51	<.0001	0.05
TRTPN (ATPTN)	2	4	1	6	5.20	<.0001	0.05
TRTPN (ATPTN)	2	4	2	6	0.75	0.4503	0.05
TRTPN (ATPTN)	2	4	1	7	11.04	<.0001	0.05
TRTPN (ATPTN)	2	4	2	7	6.89	<.0001	0.05
TRTPN (ATPTN)	2	4	1	8	22.40	<.0001	0.05
TRTPN (ATPTN)	2	4	2	8	20.84	<.0001	0.05
TRTPN (ATPTN)	2	4	1	9	24.31	<.0001	0.05
TRTPN (ATPTN)	2	4	2	9	24.48	<.0001	0.05
TRTPN (ATPTN)	1	5	2	5	-3.16	0.0016	0.05
TRTPN (ATPTN)	1	5	1	6	-17.57	<.0001	0.05
TRTPN (ATPTN)	1	5	2	6	-15.78	<.0001	0.05
TRTPN (ATPTN)	1	5	1	7	-8.48	<.0001	0.05
TRTPN (ATPTN)	1	5	2	7	-10.05	<.0001	0.05
TRTPN (ATPTN)	1	5	1	8	8.96	<.0001	0.05
TRTPN (ATPTN)	1	5	2	8	2.77	0.0057	0.05
TRTPN (ATPTN)	1	5	1	9	11.84	<.0001	0.05
TRTPN (ATPTN)	1	5	2	9	5.95	<.0001	0.05
TRTPN (ATPTN)	2	5	1	6	-8.21	<.0001	0.05
TRTPN (ATPTN)	2	5	2	6	-13.63	<.0001	0.05
TRTPN (ATPTN)	2	5	1	7	-2.35	0.0189	0.05
TRTPN (ATPTN)	2	5	2	7	-7.46	<.0001	0.05
TRTPN (ATPTN)	2	5	1	8	8.97	<.0001	0.05
TRTPN (ATPTN)	2	5	2	8	6.39	<.0001	0.05
TRTPN (ATPTN)	2	5	1	9	10.81	<.0001	0.05
TRTPN (ATPTN)	2	5	2	9	9.85	<.0001	0.05
TRTPN (ATPTN)	1	6	2	6	-4.46	<.0001	0.05
TRTPN (ATPTN)	1	6	1	7	8.98	<.0001	0.05
TRTPN (ATPTN)	1	6	2	7	1.23	0.2196	0.05
TRTPN (ATPTN)	1	6	1	8	26.38	<.0001	0.05
TRTPN (ATPTN)	1	6	2	8	14.08	<.0001	0.05
TRTPN (ATPTN)	1	6	1	9	29.44	<.0001	0.05
TRTPN (ATPTN)	1	6	2	9	17.38	<.0001	0.05
TRTPN (ATPTN)	2	6	1	7	10.25	<.0001	0.05
TRTPN (ATPTN)	2	6	2	7	6.09	<.0001	0.05
TRTPN (ATPTN)	2	6	1	8	21.52	<.0001	0.05
TRTPN (ATPTN)	2	6	2	8	19.91	<.0001	0.05
TRTPN (ATPTN)	2	6	1	9	23.41	<.0001	0.05
TRTPN (ATPTN)	2	6	2	9	23.48	<.0001	0.05
TRTPN (ATPTN)	1	7	2	7	-4.56	<.0001	0.05
TRTPN (ATPTN)	1	7	1	8	17.31	<.0001	0.05
TRTPN (ATPTN)	1	7	2	8	8.24	<.0001	0.05
TRTPN (ATPTN)	1	7	1	9	20.24	<.0001	0.05
TRTPN (ATPTN)	1	7	2	9	11.46	<.0001	0.05
TRTPN (ATPTN)	2	7	1	8	15.79	<.0001	0.05
TRTPN (ATPTN)	2	7	2	8	13.75	<.0001	0.05
TRTPN (ATPTN)	2	7	1	9	17.65	<.0001	0.05
TRTPN (ATPTN)	2	7	2	9	17.24	<.0001	0.05
TRTPN (ATPTN)	1	8	2	8	-3.04	0.0024	0.05
TRTPN (ATPTN)	1	8	1	9	2.76	0.0059	0.05
TRTPN (ATPTN)	1	8	2	9	0.07	0.9420	0.05
TRTPN (ATPTN)	2	8	1	9	4.84	<.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	8	2	9	3.38	0.0007	0.05
TRTPN (ATPTN)	1	9	2	9	-1.73	0.0833	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	-17.3012	-1.0719
TRTPN (ATPTN)	1	1	1	2	-77.4025	-66.8207
TRTPN (ATPTN)	1	1	2	2	-103.08	-86.6565
TRTPN (ATPTN)	1	1	1	3	-30.7993	-20.2263
TRTPN (ATPTN)	1	1	2	3	-56.7901	-40.3659
TRTPN (ATPTN)	1	1	1	4	-80.5382	-69.9648
TRTPN (ATPTN)	1	1	2	4	-109.69	-93.3704
TRTPN (ATPTN)	1	1	1	5	-37.6195	-27.0463
TRTPN (ATPTN)	1	1	2	5	-53.7382	-37.3681
TRTPN (ATPTN)	1	1	1	6	-85.1576	-74.5739
TRTPN (ATPTN)	1	1	2	6	-106.83	-90.3741
TRTPN (ATPTN)	1	1	1	7	-60.7324	-50.0791
TRTPN (ATPTN)	1	1	2	7	-82.9433	-66.4359
TRTPN (ATPTN)	1	1	1	8	-13.2480	-2.5843
TRTPN (ATPTN)	1	1	2	8	-28.9354	-12.4824
TRTPN (ATPTN)	1	1	1	9	-5.6888	4.8528
TRTPN (ATPTN)	1	1	2	9	-15.7546	0.5293
TRTPN (ATPTN)	2	1	1	2	-71.0522	-54.7980
TRTPN (ATPTN)	2	1	2	2	-93.2435	-78.1208
TRTPN (ATPTN)	2	1	1	3	-24.4506	-8.2020
TRTPN (ATPTN)	2	1	2	3	-46.9527	-31.8302
TRTPN (ATPTN)	2	1	1	4	-74.1894	-57.9405
TRTPN (ATPTN)	2	1	2	4	-99.8429	-84.8395
TRTPN (ATPTN)	2	1	1	5	-31.2707	-15.0220
TRTPN (ATPTN)	2	1	2	5	-43.8984	-28.8347
TRTPN (ATPTN)	2	1	1	6	-78.8069	-62.5515
TRTPN (ATPTN)	2	1	2	6	-96.9897	-81.8372
TRTPN (ATPTN)	2	1	1	7	-54.3697	-38.0688
TRTPN (ATPTN)	2	1	2	7	-73.1096	-57.8966
TRTPN (ATPTN)	2	1	1	8	-6.8835	9.4242
TRTPN (ATPTN)	2	1	2	8	-19.0993	-3.9454
TRTPN (ATPTN)	2	1	1	9	0.6544	16.8826
TRTPN (ATPTN)	2	1	2	9	-5.9110	9.0588
TRTPN (ATPTN)	1	2	2	2	-30.9818	-14.5323
TRTPN (ATPTN)	1	2	1	3	41.2945	51.9031
TRTPN (ATPTN)	1	2	2	3	15.3088	31.7585
TRTPN (ATPTN)	1	2	1	4	-8.4444	2.1646
TRTPN (ATPTN)	1	2	2	4	-37.5863	-21.2459
TRTPN (ATPTN)	1	2	1	5	34.4744	45.0831
TRTPN (ATPTN)	1	2	2	5	18.3606	34.7564
TRTPN (ATPTN)	1	2	1	6	-13.0637	-2.4445
TRTPN (ATPTN)	1	2	2	6	-34.7270	-18.2497
TRTPN (ATPTN)	1	2	1	7	11.3615	22.0503
TRTPN (ATPTN)	1	2	2	7	-10.8444	5.6884
TRTPN (ATPTN)	1	2	1	8	58.8470	69.5440
TRTPN (ATPTN)	1	2	2	8	43.1635	59.6420
TRTPN (ATPTN)	1	2	1	9	66.4027	76.9845
TRTPN (ATPTN)	1	2	2	9	56.3441	72.6538

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)	2	2	1	3	61.1337	77.5781
TRTPN (ATPTN)	2	2	2	3	38.6471	53.9343
TRTPN (ATPTN)	2	2	1	4	11.3948	27.8396
TRTPN (ATPTN)	2	2	2	4	-14.2472	0.9291
TRTPN (ATPTN)	2	2	1	5	54.3136	70.7581
TRTPN (ATPTN)	2	2	2	5	41.6983	56.9329
TRTPN (ATPTN)	2	2	1	6	6.7773	23.2285
TRTPN (ATPTN)	2	2	2	6	-11.3851	3.9225
TRTPN (ATPTN)	2	2	1	7	31.2149	47.7109
TRTPN (ATPTN)	2	2	2	7	12.4953	27.8629
TRTPN (ATPTN)	2	2	1	8	78.7012	95.2038
TRTPN (ATPTN)	2	2	2	8	66.5021	81.8174
TRTPN (ATPTN)	2	2	1	9	86.2385	102.66
TRTPN (ATPTN)	2	2	2	9	79.6733	94.8387
TRTPN (ATPTN)	1	3	2	3	-31.2872	-14.8432
TRTPN (ATPTN)	1	3	1	4	-55.0370	-44.4405
TRTPN (ATPTN)	1	3	2	4	-84.1824	-67.8475
TRTPN (ATPTN)	1	3	1	5	-12.1182	-1.5220
TRTPN (ATPTN)	1	3	2	5	-28.2354	-11.8452
TRTPN (ATPTN)	1	3	1	6	-59.6563	-49.0497
TRTPN (ATPTN)	1	3	2	6	-81.3230	-64.8513
TRTPN (ATPTN)	1	3	1	7	-35.2301	-24.5559
TRTPN (ATPTN)	1	3	2	7	-57.4405	-40.9131
TRTPN (ATPTN)	1	3	1	8	12.2533	22.9399
TRTPN (ATPTN)	1	3	2	8	-3.4326	13.0404
TRTPN (ATPTN)	1	3	1	9	19.8082	30.3813
TRTPN (ATPTN)	1	3	2	9	9.7481	26.0522
TRTPN (ATPTN)	2	3	1	4	-34.8958	-18.4512
TRTPN (ATPTN)	2	3	2	4	-60.5424	-45.3571
TRTPN (ATPTN)	2	3	1	5	8.0230	24.4673
TRTPN (ATPTN)	2	3	2	5	-4.5845	10.6342
TRTPN (ATPTN)	2	3	1	6	-39.5132	-23.0623
TRTPN (ATPTN)	2	3	2	6	-57.6795	-42.3645
TRTPN (ATPTN)	2	3	1	7	-15.0757	1.4201
TRTPN (ATPTN)	2	3	2	7	-33.7992	-18.4241
TRTPN (ATPTN)	2	3	1	8	32.4106	48.9131
TRTPN (ATPTN)	2	3	2	8	20.2179	35.5202
TRTPN (ATPTN)	2	3	1	9	39.9479	56.3720
TRTPN (ATPTN)	2	3	2	9	33.3828	48.5479
TRTPN (ATPTN)	1	4	2	4	-34.4440	-18.1084
TRTPN (ATPTN)	1	4	1	5	37.6203	48.2170
TRTPN (ATPTN)	1	4	2	5	21.5031	37.8936
TRTPN (ATPTN)	1	4	1	6	-9.9167	0.6882
TRTPN (ATPTN)	1	4	2	6	-31.5845	-15.1125
TRTPN (ATPTN)	1	4	1	7	14.5074	25.1841
TRTPN (ATPTN)	1	4	2	7	-7.7019	8.8257
TRTPN (ATPTN)	1	4	1	8	61.9919	72.6788
TRTPN (ATPTN)	1	4	2	8	46.3059	62.7793
TRTPN (ATPTN)	1	4	1	9	69.5467	80.1202
TRTPN (ATPTN)	1	4	2	9	59.4867	75.7910
TRTPN (ATPTN)	2	4	1	5	61.0274	77.3624
TRTPN (ATPTN)	2	4	2	5	48.4114	63.5379
TRTPN (ATPTN)	2	4	1	6	13.4911	29.8328
TRTPN (ATPTN)	2	4	2	6	-4.6753	10.5308
TRTPN (ATPTN)	2	4	1	7	37.9285	54.3154
TRTPN (ATPTN)	2	4	2	7	19.2050	34.4713
TRTPN (ATPTN)	2	4	1	8	85.4148	101.81
TRTPN (ATPTN)	2	4	2	8	73.2151	88.4226
TRTPN (ATPTN)	2	4	1	9	92.9524	109.27

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)	2	4	2	9	86.3920	101.44
TRTPN (ATPTN)	1	5	2	5	-21.4155	-5.0250
TRTPN (ATPTN)	1	5	1	6	-52.8363	-42.2295
TRTPN (ATPTN)	1	5	2	6	-74.5030	-58.0312
TRTPN (ATPTN)	1	5	1	7	-28.4099	-17.7359
TRTPN (ATPTN)	1	5	2	7	-50.6205	-34.0930
TRTPN (ATPTN)	1	5	1	8	19.0745	29.7589
TRTPN (ATPTN)	1	5	2	8	3.3874	19.8605
TRTPN (ATPTN)	1	5	1	9	26.6282	37.2014
TRTPN (ATPTN)	1	5	2	9	16.5681	32.8723
TRTPN (ATPTN)	2	5	1	6	-42.5111	-26.1142
TRTPN (ATPTN)	2	5	2	6	-60.6751	-45.4187
TRTPN (ATPTN)	2	5	1	7	-18.0737	-1.6316
TRTPN (ATPTN)	2	5	2	7	-36.7948	-21.4782
TRTPN (ATPTN)	2	5	1	8	29.4126	45.8613
TRTPN (ATPTN)	2	5	2	8	17.2193	32.4692
TRTPN (ATPTN)	2	5	1	9	36.9501	53.3201
TRTPN (ATPTN)	2	5	2	9	30.3873	45.4936
TRTPN (ATPTN)	1	6	2	6	-26.9735	-10.4950
TRTPN (ATPTN)	1	6	1	7	19.1166	29.8033
TRTPN (ATPTN)	1	6	2	7	-3.0909	13.4432
TRTPN (ATPTN)	1	6	1	8	66.6011	77.2981
TRTPN (ATPTN)	1	6	2	8	50.9170	67.3967
TRTPN (ATPTN)	1	6	1	9	74.1559	84.7395
TRTPN (ATPTN)	1	6	2	9	64.0976	80.4086
TRTPN (ATPTN)	2	6	1	7	34.9326	51.4559
TRTPN (ATPTN)	2	6	2	7	16.2086	31.6121
TRTPN (ATPTN)	2	6	1	8	82.4188	98.9488
TRTPN (ATPTN)	2	6	2	8	70.2227	85.5595
TRTPN (ATPTN)	2	6	1	9	89.9561	106.41
TRTPN (ATPTN)	2	6	2	9	83.3898	98.5849
TRTPN (ATPTN)	1	7	2	7	-27.5732	-10.9945
TRTPN (ATPTN)	1	7	1	8	42.1096	52.8696
TRTPN (ATPTN)	1	7	2	8	26.4346	42.9591
TRTPN (ATPTN)	1	7	1	9	49.6611	60.3144
TRTPN (ATPTN)	1	7	2	9	39.6150	55.9712
TRTPN (ATPTN)	2	7	1	8	58.4808	75.0661
TRTPN (ATPTN)	2	7	2	8	46.2823	61.6792
TRTPN (ATPTN)	2	7	1	9	66.0179	82.5252
TRTPN (ATPTN)	2	7	2	9	59.4492	74.7047
TRTPN (ATPTN)	1	8	2	8	-21.0583	-4.5272
TRTPN (ATPTN)	1	8	1	9	2.1663	12.8300
TRTPN (ATPTN)	1	8	2	9	-7.8779	8.4850
TRTPN (ATPTN)	2	8	1	9	12.0644	28.5173
TRTPN (ATPTN)	2	8	2	9	5.4980	20.6945
TRTPN (ATPTN)	1	9	2	9	-15.3368	0.9475

19: Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	443

Number of Observations

Number of Observations Read	453
Number of Observations Used	443
Number of Observations Not Used	10

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2.4827

Fit Statistics

-2 Res Log Likelihood	1668.3
AIC (Smaller is Better)	1670.3
AICC (Smaller is Better)	1670.3
BIC (Smaller is Better)	1674.4

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	7.2884	0.3649	439	19.97
trtpn		1	-0.9761	0.1585	439	-6.16
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.02534	0.1500	439	-0.17
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.1399	0.03066	439	4.56

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PSMPGM

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8659	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			6.5712	8.0055
trtpn		1	-1.2877	-0.6645
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.3201	0.2695
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.07968	0.2002

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	439	37.90	<.0001
PREAD	1	439	0.03	0.8659
BASE	1	439	20.83	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	7.8491	0.09191	439	85.40	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	8.8252	0.1291	439	68.34	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	7.6685	8.0298	2563.52	2139.86	3071.06
trtpn	LSMeans, IDeg	8.5714	9.0790	6803.49	5278.49	8769.08

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.9761	0.1585	439	-6.16

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PSMPGM

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-1.2877	-0.6645	0.3768

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.2759	0.5146

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	443

Number of Observations

Number of Observations Read	453
Number of Observations Used	443
Number of Observations Not Used	10

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	806.17

Fit Statistics

-2 Res Log Likelihood	4212.8
AIC (Smaller is Better)	4214.8
AICC (Smaller is Better)	4214.8
BIC (Smaller is Better)	4218.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			131.34	6.5753	439	19.97
trtpn		1	-17.5886	2.8570	439	-6.16
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.4567	2.7030	439	-0.17
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.1399	0.03066	439	4.56

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9SMPGMU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8659	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			118.41	144.26
trtpn		1	-23.2036	-11.9735
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-5.7691	4.8557
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.07968	0.2002

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	439	37.90	<.0001
PREAD	1	439	0.03	0.8659
BASE	1	439	20.83	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	141.44	1.6563	439	85.40	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	159.03	2.3270	439	68.34	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	138.19	144.70	2.674E61	1.032E60	6.933E62
trtpn	LSMeans, IDeg	154.46	163.60	1.164E69	1.201E67	1.127E71

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-17.5886	2.8570	439	-6.16

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9SMPGMU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	<.0001	0.05	-23.2036	-11.9735	2.298E-8

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	8.37E-11	6.309E-6

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	443

Number of Observations

Number of Observations Read	453
Number of Observations Used	443
Number of Observations Not Used	10

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2.4827

Fit Statistics

-2 Res Log Likelihood	1668.3
AIC (Smaller is Better)	1670.3
AICC (Smaller is Better)	1670.3
BIC (Smaller is Better)	1674.4

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			7.2884	0.3649	439	19.97
trtpn		1	-0.9761	0.1585	439	-6.16
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.02534	0.1500	439	-0.17
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.8601	0.03066	439	-28.05

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PSMPGM

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8659	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			6.5712	8.0055
trtpn		1	-1.2877	-0.6645
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.3201	0.2695
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.9203	-0.7998

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	439	37.90	<.0001
PREAD	1	439	0.03	0.8659
BASE	1	439	786.85	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-3.2198	0.09191	439	-35.03	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	-2.2437	0.1291	439	-17.38	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-3.4004	-3.0391
trtpn	Change from baseline, IDeg	0.05	-2.4975	-1.9899

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	443

Number of Observations

Number of Observations Read	453
Number of Observations Used	443
Number of Observations Not Used	10

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	806.17

Fit Statistics

-2 Res Log Likelihood	4212.8
AIC (Smaller is Better)	4214.8
AICC (Smaller is Better)	4214.8
BIC (Smaller is Better)	4218.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			131.34	6.5753	439	19.97
trtpn		1	-17.5886	2.8570	439	-6.16
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.4567	2.7030	439	-0.17
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.8601	0.03066	439	-28.05

Mean of 9-point self-measured plasma glucose profile after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9SMPGMU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8659	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			118.41	144.26
trtpn		1	-23.2036	-11.9735
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-5.7691	4.8557
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.9203	-0.7998

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	439	37.90	<.0001
PREAD	1	439	0.03	0.8659
BASE	1	439	786.84	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-58.0206	1.6563	439	-35.03	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	-40.4320	2.3270	439	-17.38	<.0001

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-61.2758	-54.7654
trtpn	Change from baseline, IDeg	0.05	-45.0054	-35.8586

20: Prandial increment after 26 weeks of treatment – 9-point self-measured plasma glucose profile – change from baseline – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 449

Number of Observations

Number of Observations Read 453
 Number of Observations Used 449
 Number of Observations Not Used 4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2154.91

Fit Statistics

-2 Res Log Likelihood 4708.0
 AIC (Smaller is Better) 4710.0
 AICC (Smaller is Better) 4710.0
 BIC (Smaller is Better) 4714.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	62.1279	5.6099	445	11.07
trtpn		1	-13.8531	4.6458	445	-2.98
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		3.8477	4.3900	445	0.88
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.2690	0.03980	445	6.76

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIBU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0030	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3813	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			51.1026	73.1532
trtpn		1	-22.9835	-4.7226
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-4.7801	12.4754
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.1908	0.3472

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	8.89	0.0030
PREAD	1	445	0.77	0.3813
BASE	1	445	45.67	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	73.0519	2.6908	445	27.15	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	86.9050	3.7824	445	22.98	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	67.7637	78.3402	5.322E31	2.688E29	1.054E34
trtpn	LSMeans, IDeg	79.4713	94.3386	5.525E37	3.266E34	9.348E40

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-13.8531	4.6458	445	-2.98

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIBU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0030	0.05	-22.9835	-4.7226	9.632E-7

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	1.04E-10	0.008892

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	446

Number of Observations

Number of Observations Read	453
Number of Observations Used	446
Number of Observations Not Used	7

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	1879.19

Fit Statistics

-2 Res Log Likelihood	4616.1
AIC (Smaller is Better)	4618.1
AICC (Smaller is Better)	4618.1
BIC (Smaller is Better)	4622.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			45.9181	4.3240	442	10.62
trtpn		1	-4.3682	4.3513	442	-1.00
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.5936	4.1296	442	-0.14
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.1500	0.03431	442	4.37

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIEU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.3160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8858	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			37.4199	54.4163
trtpn		1	-12.9200	4.1836
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-8.7098	7.5226
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.08253	0.2174

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	442	1.01	0.3160
PREAD	1	442	0.02	0.8858
BASE	1	442	19.10	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	47.7303	2.5209	442	18.93	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	52.0985	3.5430	442	14.70	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	42.7758	52.6848	5.358E20	3.778E18	7.598E22
trtpn	LSMeans, IDeg	45.1352	59.0618	4.228E22	3.999E19	4.469E25

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-4.3682	4.3513	442	-1.00

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIEU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.3160	0.05	-12.9200	4.1836	0.01267

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	2.449E-6	65.6022

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2310.04

Fit Statistics

-2 Res Log Likelihood	4739.1
AIC (Smaller is Better)	4741.1
AICC (Smaller is Better)	4741.1
BIC (Smaller is Better)	4745.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			44.9769	4.7616	445	9.45
trtpn		1	-1.2247	4.8065	445	-0.25
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-4.4637	4.5624	445	-0.98
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.2018	0.03834	445	5.26

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGILU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.7990	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3284	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			35.6189	54.3350
trtpn		1	-10.6710	8.2215
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-13.4301	4.5028
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.1264	0.2771

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	0.06	0.7990
PREAD	1	445	0.96	0.3284
BASE	1	445	27.70	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	50.1525	2.7853	445	18.01	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	51.3772	3.9142	445	13.13	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	44.6786	55.6264	6.039E21	2.533E19	1.44E24
trtpn	LSMeans, IDeg	43.6845	59.0699	2.055E22	9.374E18	4.505E25

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-1.2247	4.8065	445	-0.25

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGILU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.7990	0.05	-10.6710	8.2215	0.2938

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.000023	3720.21

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	452

Number of Observations

Number of Observations Read	453
Number of Observations Used	452
Number of Observations Not Used	1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2.9392

Fit Statistics

-2 Res Log Likelihood	1777.4
AIC (Smaller is Better)	1779.4
AICC (Smaller is Better)	1779.4
BIC (Smaller is Better)	1783.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			2.7808	0.2026	448	13.73
trtpn		1	-0.4039	0.1715	448	-2.36
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.09210	0.1624	448	-0.57
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.2575	0.03900	448	6.60

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINC

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0189	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.5709	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.3826	3.1789
trtpn		1	-0.7410	-0.06690
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4112	0.2271
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.1808	0.3341

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	5.55	0.0189
PREAD	1	448	0.32	0.5709
BASE	1	448	43.59	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	3.1460	0.09892	448	31.80	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	3.5500	0.1398	448	25.39	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	2.9516	3.3404	23.2435	19.1370	28.2313
trtpn	LSMeans, IDeg	3.2752	3.8247	34.8123	26.4488	45.8205

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.4039	0.1715	448	-2.36

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINC

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0189	0.05	-0.7410	-0.06690	0.6677

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.4766	0.9353

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	6.6362

Fit Statistics

-2 Res Log Likelihood	2128.8
AIC (Smaller is Better)	2130.8
AICC (Smaller is Better)	2130.8
BIC (Smaller is Better)	2134.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			3.4477	0.3113	445	11.07
trtpn		1	-0.7688	0.2578	445	-2.98
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.2135	0.2436	445	0.88
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.2690	0.03980	445	6.76

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCB

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0030	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3813	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.8359	4.0596
trtpn		1	-1.2754	-0.2621
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.2653	0.6923
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.1908	0.3472

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	8.89	0.0030
PREAD	1	445	0.77	0.3813
BASE	1	445	45.67	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	4.0539	0.1493	445	27.15	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	4.8227	0.2099	445	22.98	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	3.7605	4.3474	57.6238	42.9686	77.2775
trtpn	LSMeans, IDeg	4.4102	5.2352	124.30	82.2838	187.77

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.7688	0.2578	445	-2.98

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCB

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0030	0.05	-1.2754	-0.2621	0.4636

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.2793	0.7695

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	446

Number of Observations

Number of Observations Read	453
Number of Observations Used	446
Number of Observations Not Used	7

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5.7871

Fit Statistics

-2 Res Log Likelihood	2054.2
AIC (Smaller is Better)	2056.2
AICC (Smaller is Better)	2056.3
BIC (Smaller is Better)	2060.3

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			2.5482	0.2400	442	10.62
trtpn		1	-0.2424	0.2415	442	-1.00
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.03294	0.2292	442	-0.14
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.1500	0.03431	442	4.37

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCE

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.3160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8858	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.0766	3.0198
trtpn		1	-0.7170	0.2322
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4833	0.4175
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.08253	0.2174

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	442	1.01	0.3160
PREAD	1	442	0.02	0.8858
BASE	1	442	19.10	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	2.6487	0.1399	442	18.93	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	2.8911	0.1966	442	14.70	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	2.3738	2.9237	14.1362	10.7381	18.6098
trtpn	LSMeans, IDeg	2.5047	3.2776	18.0140	12.2402	26.5113

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.2424	0.2415	442	-1.00

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCE

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.3160	0.05	-0.7170	0.2322	0.7847

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.4882	1.2613

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	7.1139

Fit Statistics

-2 Res Log Likelihood	2159.9
AIC (Smaller is Better)	2161.9
AICC (Smaller is Better)	2161.9
BIC (Smaller is Better)	2166.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			2.4959	0.2642	445	9.45
trtpn		1	-0.06796	0.2667	445	-0.25
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2477	0.2532	445	-0.98
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.2018	0.03834	445	5.26

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCL

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.7990	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3284	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.9766	3.0153
trtpn		1	-0.5922	0.4562
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.7453	0.2499
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.1264	0.2771

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	0.06	0.7990
PREAD	1	445	0.96	0.3284
BASE	1	445	27.70	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	2.7832	0.1546	445	18.01	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	2.8511	0.2172	445	13.13	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	2.4794	3.0869	16.1700	11.9340	21.9096
trtpn	LSMeans, IDeg	2.4242	3.2780	17.3072	11.2935	26.5232

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-0.06796	0.2667	445	-0.25

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCL

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.7990	0.05	-0.5922	0.4562	0.9343

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.5531	1.5781

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	452

Number of Observations

Number of Observations Read	453
Number of Observations Used	452
Number of Observations Not Used	1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	954.43

Fit Statistics

-2 Res Log Likelihood	4373.9
AIC (Smaller is Better)	4375.9
AICC (Smaller is Better)	4376.0
BIC (Smaller is Better)	4380.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			50.1099	3.6507	448	13.73
trtpn		1	-7.2791	3.0904	448	-2.36
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-1.6597	2.9264	448	-0.57
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.2575	0.03900	448	6.60

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0189	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.5709	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			42.9353	57.2845
trtpn		1	-13.3526	-1.2055
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-7.4108	4.0914
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.1808	0.3341

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	5.55	0.0189
PREAD	1	448	0.32	0.5709
BASE	1	448	43.59	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	56.6914	1.7825	448	31.80	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	63.9705	2.5193	448	25.39	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	53.1882	60.1946	4.176E24	1.257E23	1.387E26
trtpn	LSMeans, IDeg	59.0193	68.9216	6.054E27	4.283E25	8.556E29

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-7.2791	3.0904	448	-2.36

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIU

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0189	0.05	-13.3526	-1.2055	0.000690

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	1.589E-6	0.2995

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2154.91

Fit Statistics

-2 Res Log Likelihood	4708.0
AIC (Smaller is Better)	4710.0
AICC (Smaller is Better)	4710.0
BIC (Smaller is Better)	4714.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			62.1279	5.6099	445	11.07
trtpn		1	-13.8531	4.6458	445	-2.98
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		3.8477	4.3900	445	0.88
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.7310	0.03980	445	-18.37

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIBU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0030	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3813	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			51.1026	73.1532
trtpn		1	-22.9835	-4.7226
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-4.7801	12.4754
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.8092	-0.6528

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	8.89	0.0030
PREAD	1	445	0.77	0.3813
BASE	1	445	337.31	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-12.3083	2.6908	445	-4.57	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	1.5448	3.7824	445	0.41	0.6832

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-17.5966	-7.0200
trtpn	Change from baseline, IDeg	0.05	-5.8889	8.9784

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	446

Number of Observations

Number of Observations Read	453
Number of Observations Used	446
Number of Observations Not Used	7

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	1879.19

Fit Statistics

-2 Res Log Likelihood	4616.1
AIC (Smaller is Better)	4618.1
AICC (Smaller is Better)	4618.1
BIC (Smaller is Better)	4622.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			45.9181	4.3240	442	10.62
trtpn		1	-4.3682	4.3513	442	-1.00
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.5936	4.1296	442	-0.14
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.8500	0.03431	442	-24.78

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIEU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.3160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8858	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			37.4199	54.4163
trtpn		1	-12.9200	4.1836
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-8.7098	7.5226
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.9175	-0.7826

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	442	1.01	0.3160
PREAD	1	442	0.02	0.8858
BASE	1	442	613.81	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	4.6278	2.5209	442	1.84	0.0671
trtpn	Change from baseline, IDeg	WORK.ADATA2	8.9960	3.5430	442	2.54	0.0115

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-0.3267	9.5823
trtpn	Change from baseline, IDeg	0.05	2.0327	15.9593

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2310.04

Fit Statistics

-2 Res Log Likelihood	4739.1
AIC (Smaller is Better)	4741.1
AICC (Smaller is Better)	4741.1
BIC (Smaller is Better)	4745.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			44.9769	4.7616	445	9.45
trtpn		1	-1.2247	4.8065	445	-0.25
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-4.4637	4.5624	445	-0.98
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.7982	0.03834	445	-20.82

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGILU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.7990	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3284	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			35.6189	54.3350
trtpn		1	-10.6710	8.2215
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-13.4301	4.5028
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.8736	-0.7229

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	0.06	0.7990
PREAD	1	445	0.96	0.3284
BASE	1	445	433.46	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	7.8878	2.7853	445	2.83	0.0048
trtpn	Change from baseline, IDeg	WORK.ADATA2	9.1125	3.9142	445	2.33	0.0204

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	2.4138	13.3617
trtpn	Change from baseline, IDeg	0.05	1.4198	16.8052

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	452

Number of Observations

Number of Observations Read	453
Number of Observations Used	452
Number of Observations Not Used	1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	2.9392

Fit Statistics

-2 Res Log Likelihood	1777.4
AIC (Smaller is Better)	1779.4
AICC (Smaller is Better)	1779.4
BIC (Smaller is Better)	1783.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	2.7808	0.2026	448	13.73
trtpn		1	-0.4039	0.1715	448	-2.36
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.09210	0.1624	448	-0.57
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.7425	0.03900	448	-19.04

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINC

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0189	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.5709	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.3826	3.1789
trtpn		1	-0.7410	-0.06690
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4112	0.2271
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.8192	-0.6659

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	5.55	0.0189
PREAD	1	448	0.32	0.5709
BASE	1	448	362.57	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-0.01168	0.09892	448	-0.12	0.9061
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.3923	0.1398	448	2.81	0.0052

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-0.2061	0.1827
trtpn	Change from baseline, IDeg	0.05	0.1175	0.6670

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	6.6362

Fit Statistics

-2 Res Log Likelihood	2128.8
AIC (Smaller is Better)	2130.8
AICC (Smaller is Better)	2130.8
BIC (Smaller is Better)	2134.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			3.4477	0.3113	445	11.07
trtpn		1	-0.7688	0.2578	445	-2.98
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.2135	0.2436	445	0.88
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.7310	0.03980	445	-18.37

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCB

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0030	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3813	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.8359	4.0596
trtpn		1	-1.2754	-0.2621
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.2653	0.6923
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.8092	-0.6528

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	8.89	0.0030
PREAD	1	445	0.77	0.3813
BASE	1	445	337.31	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-0.6830	0.1493	445	-4.57	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.08572	0.2099	445	0.41	0.6832

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-0.9765	-0.3896
trtpn	Change from baseline, IDeg	0.05	-0.3268	0.4982

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	446

Number of Observations

Number of Observations Read	453
Number of Observations Used	446
Number of Observations Not Used	7

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	5.7871

Fit Statistics

-2 Res Log Likelihood	2054.2
AIC (Smaller is Better)	2056.2
AICC (Smaller is Better)	2056.3
BIC (Smaller is Better)	2060.3

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			2.5482	0.2400	442	10.62
trtpn		1	-0.2424	0.2415	442	-1.00
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.03294	0.2292	442	-0.14
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.8500	0.03431	442	-24.78

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCE

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.3160	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8858	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.0766	3.0198
trtpn		1	-0.7170	0.2322
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.4833	0.4175
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.9175	-0.7826

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	442	1.01	0.3160
PREAD	1	442	0.02	0.8858
BASE	1	442	613.81	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	0.2568	0.1399	442	1.84	0.0671
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.4992	0.1966	442	2.54	0.0115

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-0.01813	0.5318
trtpn	Change from baseline, IDeg	0.05	0.1128	0.8856

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	7.1139

Fit Statistics

-2 Res Log Likelihood	2159.9
AIC (Smaller is Better)	2161.9
AICC (Smaller is Better)	2161.9
BIC (Smaller is Better)	2166.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			2.4959	0.2642	445	9.45
trtpn		1	-0.06796	0.2667	445	-0.25
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2477	0.2532	445	-0.98
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.7982	0.03834	445	-20.82

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGINCL

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.7990	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.3284	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.9766	3.0153
trtpn		1	-0.5922	0.4562
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.7453	0.2499
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.8736	-0.7229

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	0.06	0.7990
PREAD	1	445	0.96	0.3284
BASE	1	445	433.46	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	0.4377	0.1546	445	2.83	0.0048
trtpn	Change from baseline, IDeg	WORK.ADATA2	0.5057	0.2172	445	2.33	0.0204

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	0.1340	0.7415
trtpn	Change from baseline, IDeg	0.05	0.07879	0.9326

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	452

Number of Observations

Number of Observations Read	453
Number of Observations Used	452
Number of Observations Not Used	1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	954.43

Fit Statistics

-2 Res Log Likelihood	4373.9
AIC (Smaller is Better)	4375.9
AICC (Smaller is Better)	4376.0
BIC (Smaller is Better)	4380.1

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			50.1099	3.6507	448	13.73
trtpn		1	-7.2791	3.0904	448	-2.36
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-1.6597	2.9264	448	-0.57
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.7425	0.03900	448	-19.04

Prandial increment after 26 weeks of treatment - 9-point self-measured plasma glucose profile - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=P9PGIU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0189	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.5709	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			42.9353	57.2845
trtpn		1	-13.3526	-1.2055
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-7.4108	4.0914
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.8192	-0.6659

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	5.55	0.0189
PREAD	1	448	0.32	0.5709
BASE	1	448	362.56	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-0.2105	1.7825	448	-0.12	0.9061
trtpn	Change from baseline, IDeg	WORK.ADATA2	7.0686	2.5193	448	2.81	0.0052

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-3.7136	3.2927
trtpn	Change from baseline, IDeg	0.05	2.1174	12.0198

21: Fasting insulin after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 452

Number of Observations

Number of Observations Read 453
 Number of Observations Used 452
 Number of Observations Not Used 1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.5659

Fit Statistics

-2 Res Log Likelihood 1037.6
 AIC (Smaller is Better) 1039.6
 AICC (Smaller is Better) 1039.6
 BIC (Smaller is Better) 1043.7

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	1.4173	0.1666	448	8.50
trtpn		1	0.2632	0.07509	448	3.50
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.01274	0.07095	448	-0.18
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.4230	0.04125	448	10.26

Fasting insulin after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=INS_TO_S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0005	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8576	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.0897	1.7448
trtpn		1	0.1156	0.4107
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1522	0.1267
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.3419	0.5041

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	12.28	0.0005
PREAD	1	448	0.03	0.8576
base_log	1	448	105.17	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	3.2281	0.04337	448	74.42	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	2.9649	0.06126	448	48.40	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	3.1428	3.3133	25.2310	23.1694	27.4761
trtpn	LSMeans, IDeg	2.8445	3.0853	19.3931	17.1935	21.8742

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	0.2632	0.07509	448	3.50	0.0005

Fasting insulin after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=INS_TO_S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	0.1156	0.4107	1.3010

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	1.1225	1.5079		

22: Fasting C-peptide after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.3774

Fit Statistics

-2 Res Log Likelihood	849.9
AIC (Smaller is Better)	851.9
AICC (Smaller is Better)	851.9
BIC (Smaller is Better)	856.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-0.9362	0.06948	445	-13.47
trtpn		1	0.2201	0.06149	445	3.58
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.04696	0.05821	445	0.81
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.7072	0.04482	445	15.78

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C74736S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0004	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4203	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-1.0728	-0.7997
trtpn		1	0.09929	0.3410
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.06745	0.1614
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.6191	0.7953

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	12.82	0.0004
PREAD	1	445	0.65	0.4203
base_log	1	445	249.02	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	-1.3460	0.03553	445	-37.88	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	-1.5661	0.05017	445	-31.21	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	-1.4158	-1.2761	0.2603	0.2427	0.2791
trtpn	LSMeans, IDeg	-1.6647	-1.4675	0.2089	0.1892	0.2305

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	0.2201	0.06149	445	3.58	0.0004

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set
- appendix

Parameter Code=C74736S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	0.09929	0.3410	1.2463

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	1.1044	1.4064		

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set
 - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	449

Number of Observations

Number of Observations Read	453
Number of Observations Used	449
Number of Observations Not Used	4

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.3774

Fit Statistics

-2 Res Log Likelihood	849.9
AIC (Smaller is Better)	851.9
AICC (Smaller is Better)	851.9
BIC (Smaller is Better)	856.0

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			-0.6126	0.05878	445	-10.42
trtpn		1	0.2201	0.06149	445	3.58
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.04696	0.05821	445	0.81
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.7072	0.04482	445	15.78

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=CPEPTI_U

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0004	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4203	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-0.7282	-0.4971
trtpn		1	0.09929	0.3410
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.06745	0.1614
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.6191	0.7953

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	445	12.82	0.0004
PREAD	1	445	0.65	0.4203
base_log	1	445	249.02	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	-0.2407	0.03553	445	-6.77	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	-0.4608	0.05017	445	-9.18	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	-0.3105	-0.1709	0.7861	0.7331	0.8429
trtpn	LSMeans, IDeg	-0.5595	-0.3622	0.6308	0.5715	0.6961

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	0.2201	0.06149	445	3.58	0.0004

Fasting C-peptide after 26 weeks of treatment - supportive statistical analysis - full analysis set
- appendix

Parameter Code=CPEPTI_U

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	0.09929	0.3410	1.2463

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	1.1044	1.4064		

23: Fasting glucagon after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	451

Number of Observations

Number of Observations Read	453
Number of Observations Used	451
Number of Observations Not Used	2

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.2747

Fit Statistics

-2 Res Log Likelihood	711.8
AIC (Smaller is Better)	713.8
AICC (Smaller is Better)	713.8
BIC (Smaller is Better)	717.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	2.5453	0.1201	447	21.19
trtpn		1	-0.03858	0.05240	447	-0.74
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.06470	0.04944	447	-1.31
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.2213	0.03481	447	6.36

Fasting glucagon after 26 weeks of treatment - supportive statistical analysis - full analysis set
 - appendix

Parameter Code=C74859P

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.4619	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1913	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			2.3093	2.7814
trtpn		1	-0.1416	0.06440
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1619	0.03246
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.1529	0.2898

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	447	0.54	0.4619
PREAD	1	447	1.71	0.1913
base_log	1	447	40.42	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	3.1743	0.03021	447	105.07	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	3.2128	0.04280	447	75.06	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	3.1149	3.2336	23.9091	22.5308	25.3717
trtpn	LSMeans, IDeg	3.1287	3.2970	24.8495	22.8447	27.0302

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.03858	0.05240	447	-0.74	0.4619

Fasting glucagon after 26 weeks of treatment - supportive statistical analysis - full analysis set
- appendix

Parameter Code=C74859P

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.1416	0.06440	0.9622

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.8680	1.0665		

24: HOMA-B after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 452

Number of Observations

Number of Observations Read 453
 Number of Observations Used 452
 Number of Observations Not Used 1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.5070

Fit Statistics

-2 Res Log Likelihood 988.5
 AIC (Smaller is Better) 990.5
 AICC (Smaller is Better) 990.5
 BIC (Smaller is Better) 994.6

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			1.8932	0.1322	448	14.32
trtpn		1	0.3901	0.07103	448	5.49
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.01262	0.06714	448	-0.19
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.3927	0.03605	448	10.89

HOMA-B after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=HOMA_BCS

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.8510	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.6334	2.1530
trtpn		1	0.2505	0.5297
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1446	0.1193
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.3218	0.4635

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	30.15	<.0001
PREAD	1	448	0.04	0.8510
base_log	1	448	118.62	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	3.5154	0.04105	448	85.64	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	3.1254	0.05796	448	53.92	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	3.4348	3.5961	33.6300	31.0237	36.4553
trtpn	LSMeans, IDeg	3.0114	3.2393	22.7680	20.3168	25.5149

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	0.3901	0.07103	448	5.49	<.0001

HOMA-B after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=HOMA_BCS

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	0.2505	0.5297	1.4771

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment ratio, IDegLira - IDeg	1.2846	1.6984

25: HDL cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.02369

Fit Statistics

-2 Res Log Likelihood -387.4
 AIC (Smaller is Better) -385.4
 AICC (Smaller is Better) -385.3
 BIC (Smaller is Better) -381.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	0.05515	0.01465	449	3.76
trtpn		1	-0.02691	0.01535	449	-1.75
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.01619	0.01449	449	-1.12
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.7660	0.02813	449	27.23

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105587S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0002	0.05
trtpn		1	0.0802	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.2643	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			0.02635	0.08395
trtpn		1	-0.05708	0.003252
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.04466	0.01228
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.7107	0.8213

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	3.07	0.0802
PREAD	1	449	1.25	0.2643
base_log	1	449	741.32	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	0.09836	0.008859	449	11.10	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	0.1253	0.01253	449	10.00	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	0.08095	0.1158	1.1034	1.0843	1.1227
trtpn	LSMeans, IDeg	0.1006	0.1499	1.1335	1.1059	1.1617

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.02691	0.01535	449	-1.75	0.0802

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105587S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.05708	0.003252	0.9734

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.9445	1.0033		

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.02369

Fit Statistics

-2 Res Log Likelihood -387.4
 AIC (Smaller is Better) -385.4
 AICC (Smaller is Better) -385.3
 BIC (Smaller is Better) -381.2

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			0.9101	0.1065	449	8.55
trtpn		1	-0.02691	0.01535	449	-1.75
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.01619	0.01449	449	-1.12
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.7660	0.02813	449	27.23

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=HDL_SU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0802	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.2643	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			0.7008	1.1194
trtpn		1	-0.05708	0.003252
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.04466	0.01228
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.7107	0.8213

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	3.07	0.0802
PREAD	1	449	1.25	0.2643
base_log	1	449	741.32	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	3.7519	0.008859	449	423.51	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	3.7788	0.01253	449	301.57	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	3.7345	3.7693	42.6008	41.8655	43.3490
trtpn	LSMeans, IDeg	3.7542	3.8034	43.7629	42.6983	44.8539

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.02691	0.01535	449	-1.75	0.0802

HDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=HDL_SU

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.05708	0.003252	0.9734

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.9445	1.0033		

26: LDL cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	443

Number of Observations

Number of Observations Read	453
Number of Observations Used	443
Number of Observations Not Used	10

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.09192

Fit Statistics

-2 Res Log Likelihood	217.4
AIC (Smaller is Better)	219.4
AICC (Smaller is Better)	219.4
BIC (Smaller is Better)	223.4

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	0.2451	0.04507	439	5.44
trtpn		1	-0.05261	0.03067	439	-1.72
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.01684	0.02889	439	0.58
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6372	0.04110	439	15.50

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105588S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0869	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.5603	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			0.1565	0.3337
trtpn		1	-0.1129	0.007660
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.03995	0.07363
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.5564	0.7179

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	439	2.94	0.0869
PREAD	1	439	0.34	0.5603
base_log	1	439	240.29	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	0.7561	0.01760	439	42.97	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	0.8087	0.02510	439	32.21	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	0.7215	0.7906	2.1299	2.0575	2.2048
trtpn	LSMeans, IDeg	0.7593	0.8580	2.2449	2.1369	2.3585

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.05261	0.03067	439	-1.72	0.0869

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105588S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.1129	0.007660	0.9487

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.8933	1.0077		

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 443

Number of Observations

Number of Observations Read 453
 Number of Observations Used 443
 Number of Observations Not Used 10

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.09192

Fit Statistics

-2 Res Log Likelihood 217.4
 AIC (Smaller is Better) 219.4
 AICC (Smaller is Better) 219.4
 BIC (Smaller is Better) 223.4

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			1.5708	0.1870	439	8.40
trtpn		1	-0.05261	0.03067	439	-1.72
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.01684	0.02889	439	0.58
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6372	0.04110	439	15.50

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=LDL_SU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0869	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.5603	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.2033	1.9382
trtpn		1	-0.1129	0.007660
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.03995	0.07363
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.5564	0.7179

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	439	2.94	0.0869
PREAD	1	439	0.34	0.5603
base_log	1	439	240.29	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	4.4096	0.01760	439	250.59	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	4.4622	0.02510	439	177.75	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	4.3750	4.4442	82.2346	79.4392	85.1283
trtpn	LSMeans, IDeg	4.4129	4.5115	86.6770	82.5043	91.0608

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.05261	0.03067	439	-1.72	0.0869

LDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=LDL_SU

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.1129	0.007660	0.9487

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.8933	1.0077		

27: VLDL cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.1867

Fit Statistics

-2 Res Log Likelihood	541.2
AIC (Smaller is Better)	543.2
AICC (Smaller is Better)	543.2
BIC (Smaller is Better)	547.3

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-0.1883	0.04107	449	-4.58
trtpn		1	-0.01158	0.04308	449	-0.27
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.07290	0.04067	449	1.79
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6095	0.03509	449	17.37

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set
 - appendix

Parameter Code=C105589S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.7881	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.0737	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-0.2690	-0.1076
trtpn		1	-0.09625	0.07308
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.00703	0.1528
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.5405	0.6784

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	0.07	0.7881
PREAD	1	449	3.21	0.0737
base_log	1	449	301.77	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	-0.2924	0.02487	449	-11.76	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	-0.2809	0.03517	449	-7.98	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	-0.3413	-0.2436	0.7464	0.7108	0.7838
trtpn	LSMeans, IDeg	-0.3500	-0.2117	0.7551	0.7047	0.8092

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.01158	0.04308	449	-0.27	0.7881

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set
- appendix

Parameter Code=C105589S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.09625	0.07308	0.9885

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.9082	1.0758		

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set
 - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.1867

Fit Statistics

-2 Res Log Likelihood 541.2
 AIC (Smaller is Better) 543.2
 AICC (Smaller is Better) 543.2
 BIC (Smaller is Better) 547.3

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	1.2385	0.1275	449	9.71
trtpn		1	-0.01158	0.04308	449	-0.27
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.07290	0.04067	449	1.79
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6095	0.03509	449	17.37

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=VLDL_SU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.7881	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.0737	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			0.9879	1.4890
trtpn		1	-0.09625	0.07308
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.00703	0.1528
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.5405	0.6784

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	0.07	0.7881
PREAD	1	449	3.21	0.0737
base_log	1	449	301.77	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	3.3611	0.02487	449	135.15	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	3.3727	0.03517	449	95.89	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	3.3122	3.4099	28.8201	27.4455	30.2637
trtpn	LSMeans, IDeg	3.3035	3.4418	29.1559	27.2086	31.2426

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.01158	0.04308	449	-0.27	0.7881

VLDL cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set
- appendix

Parameter Code=VLDL_SU

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.09625	0.07308	0.9885

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.9082	1.0758		

28: Triglycerides after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.2371

Fit Statistics

-2 Res Log Likelihood	648.7
AIC (Smaller is Better)	650.7
AICC (Smaller is Better)	650.7
BIC (Smaller is Better)	654.8

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	0.1298	0.05020	449	2.59
trtpn		1	-0.01325	0.04855	449	-0.27
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.06990	0.04585	449	1.52
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6028	0.03500	449	17.22

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C64812S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			0.0100	0.05
trtpn		1	0.7851	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1281	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			0.03115	0.2285
trtpn		1	-0.1087	0.08216
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.02021	0.1600
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.5340	0.6716

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	0.07	0.7851
PREAD	1	449	2.32	0.1281
base_log	1	449	296.62	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	0.5207	0.02802	449	18.58	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	0.5340	0.03963	449	13.47	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	0.4657	0.5758	1.6833	1.5931	1.7786
trtpn	LSMeans, IDeg	0.4561	0.6119	1.7057	1.5779	1.8439

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.01325	0.04855	449	-0.27	0.7851

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C64812S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.1087	0.08216	0.9868

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.8970	1.0856		

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.2371

Fit Statistics

-2 Res Log Likelihood	648.7
AIC (Smaller is Better)	650.7
AICC (Smaller is Better)	650.7
BIC (Smaller is Better)	654.8

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			1.9126	0.1840	449	10.40
trtpn		1	-0.01325	0.04855	449	-0.27
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.06990	0.04585	449	1.52
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6028	0.03500	449	17.22

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=TRIG_SU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.7851	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1281	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.5511	2.2741
trtpn		1	-0.1087	0.08216
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.02021	0.1600
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.5340	0.6716

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	0.07	0.7851
PREAD	1	449	2.32	0.1281
base_log	1	449	296.62	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	5.0094	0.02802	449	178.76	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	5.0226	0.03963	449	126.73	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	4.9543	5.0645	149.81	141.78	158.29
trtpn	LSMeans, IDeg	4.9447	5.1005	151.81	140.43	164.11

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.01325	0.04855	449	-0.27	0.7851

Triglycerides after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=TRIG_SU

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.1087	0.08216	0.9868

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.8970	1.0856		

29: Total cholesterol after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.03056

Fit Statistics

-2 Res Log Likelihood	-273.4
AIC (Smaller is Better)	-271.4
AICC (Smaller is Better)	-271.4
BIC (Smaller is Better)	-267.3

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	0.4374	0.05797	449	7.55
trtpn		1	-0.03841	0.01743	449	-2.20
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.02172	0.01647	449	1.32
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6782	0.03724	449	18.21

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C105586S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0281	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1879	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			0.3235	0.5513
trtpn		1	-0.07267	-0.00415
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.01064	0.05409
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.6050	0.7513

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	4.86	0.0281
PREAD	1	449	1.74	0.1879
base_log	1	449	331.61	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	1.4326	0.01006	449	142.39	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	1.4710	0.01423	449	103.37	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	1.4128	1.4523	4.1895	4.1075	4.2731
trtpn	LSMeans, IDeg	1.4430	1.4990	4.3535	4.2335	4.4770

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.03841	0.01743	449	-2.20	0.0281

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set
- appendix

Parameter Code=C105586S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.07267	-0.00415	0.9623

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.9299	0.9959		

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set
 - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.03056

Fit Statistics

-2 Res Log Likelihood -273.4
 AIC (Smaller is Better) -271.4
 AICC (Smaller is Better) -271.4
 BIC (Smaller is Better) -267.3

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			1.6132	0.1924	449	8.39
trtpn		1	-0.03841	0.01743	449	-2.20
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		0.02172	0.01647	449	1.32
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.6782	0.03724	449	18.21

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=T_CHOL_U

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0281	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1879	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.2352	1.9913
trtpn		1	-0.07267	-0.00415
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.01064	0.05409
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.6050	0.7513

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	4.86	0.0281
PREAD	1	449	1.74	0.1879
base_log	1	449	331.61	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	5.0861	0.01006	449	505.54	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	5.1245	0.01423	449	360.12	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	5.0663	5.1059	161.76	158.59	164.99
trtpn	LSMeans, IDeg	5.0965	5.1525	168.09	163.45	172.86

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.03841	0.01743	449	-2.20	0.0281

Total cholesterol after 26 weeks of treatment - supportive statistical analysis - full analysis set
- appendix

Parameter Code=T_CHOL_U

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.07267	-0.00415	0.9623

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.9299	0.9959		

30: Free fatty acid after 26 weeks of treatment – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	452

Number of Observations

Number of Observations Read	453
Number of Observations Used	452
Number of Observations Not Used	1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.2601

Fit Statistics

-2 Res Log Likelihood	688.4
AIC (Smaller is Better)	690.4
AICC (Smaller is Better)	690.4
BIC (Smaller is Better)	694.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	-1.1035	0.06468	448	-17.06
trtpn		1	-0.01181	0.05099	448	-0.23
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.03834	0.04808	448	-0.80
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.2370	0.04606	448	5.15

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C80200S

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.8170	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4256	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			-1.2306	-0.9764
trtpn		1	-0.1120	0.08841
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1328	0.05615
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.1465	0.3275

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	0.05	0.8170
PREAD	1	448	0.64	0.4256
base_log	1	448	26.48	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	-1.3590	0.02936	448	-46.29	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	-1.3472	0.04167	448	-32.33	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	-1.4167	-1.3013	0.2569	0.2425	0.2722
trtpn	LSMeans, IDeg	-1.4291	-1.2653	0.2600	0.2395	0.2822

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.01181	0.05099	448	-0.23	0.8170

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=C80200S

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.1120	0.08841	0.9883

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.8940	1.0924		

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 452

Number of Observations

Number of Observations Read 453
 Number of Observations Used 452
 Number of Observations Not Used 1

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	0.2601

Fit Statistics

-2 Res Log Likelihood 688.4
 AIC (Smaller is Better) 690.4
 AICC (Smaller is Better) 690.4
 BIC (Smaller is Better) 694.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			1.4444	0.1203	448	12.01
trtpn		1	-0.01181	0.05099	448	-0.23
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.03834	0.04808	448	-0.80
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
base_log			0.2370	0.04606	448	5.15

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=FFAU

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.8170	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.4256	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			1.2080	1.6809
trtpn		1	-0.1120	0.08841
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.1328	0.05615
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
base_log			0.1465	0.3275

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	448	0.05	0.8170
PREAD	1	448	0.64	0.4256
base_log	1	448	26.48	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	1.9803	0.02936	448	67.45	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	1.9921	0.04167	448	47.81	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	1.9226	2.0380	7.2452	6.8390	7.6755
trtpn	LSMeans, IDeg	1.9102	2.0740	7.3312	6.7548	7.9568

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Treatment ratio, IDegLira - IDeg	WORK.ADATA2	-0.01181	0.05099	448	-0.23	0.8170

Free fatty acid after 26 weeks of treatment - supportive statistical analysis - full analysis set - appendix

Parameter Code=FFAU

The Mixed Procedure

Least Squares Means Estimate					
Effect	Label	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment ratio, IDegLira - IDeg	0.05	-0.1120	0.08841	0.9883

Least Squares Means Estimate					
Effect	Label	Exponentiated Lower	Exponentiated Upper		
trtpn	Treatment ratio, IDegLira - IDeg	0.8940	1.0924		

31: 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	453
Number of Observations Used	452
Missing Values	1

Class Level Information

Class	Levels	Values
TRTPN	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Parameter Information

Parameter	Effect	TRTPN	PREAD
Prm1	Intercept		
Prm2	TRTPN	1	
Prm3	TRTPN	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD

Iteration History For Parameter Estimates

Iter	Ridge	Log Likelihood	Prm1	Prm2	Prm4	Dispersion
0	0	-272.05183	4.8722249	-0.133255	0.0535432	0.9030346
1	1	-210.31256	4.3017337	-0.38207	-0.019395	0.5621385
2	1	-196.63064	4.0111682	-0.544379	0.0204517	0.7702072
3	0.06	-192.79932	4.0350243	-0.558915	0.0141844	6.3310514
4	0	-189.55465	3.6343238	-0.650209	0.3457195	3.2510687
5	0	-189.37048	3.755194	-0.639949	0.2514424	3.1348703
6	0	-189.3701	3.7514615	-0.640906	0.2552308	3.154036
7	0	-189.3701	3.7514508	-0.640908	0.2552416	3.1540135

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	449	191.5532	0.4266
Scaled Deviance	449	191.5532	0.4266
Pearson Chi-Square	449	572.5233	1.2751
Scaled Pearson X2	449	572.5233	1.2751
Log Likelihood		-189.3701	
Full Log Likelihood		-208.8157	
AIC (smaller is better)		425.6314	
AICC (smaller is better)		425.7209	
BIC (smaller is better)		442.0862	

Hypoglycaemic episodes - treatment emergent - confirmatory statistical analysis - full analysis set

Parameter Code=HYCNFSE

The GENMOD Procedure

Last Evaluation Of The Negative Of The Gradient and Hessian

	Prm1	Prm2	Prm4	Dispersion
Gradient	-4.23E-11	1.307E-10	-5.34E-11	-1.11E-10
Prm1	47.012506	26.834407	24.205977	-0.177861
Prm2	26.834407	26.834407	13.519355	-0.138454
Prm4	24.205977	13.519355	24.205977	-0.132367
Dispersion	-0.177861	-0.138454	-0.132367	0.8529003

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	
Intercept	1	3.7515	0.2710	3.2202	4.2827
TRTPN 1	1	-0.6409	0.2948	-1.2187	-0.0632
TRTPN 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.2552	0.2919	-0.3170	0.8274
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
Dispersion	1	3.1540	1.0834	1.6087	6.1837

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Chi-Square	Wald Pr > ChiSq
Intercept	191.58	<.0001
TRTPN 1	4.73	0.0297
TRTPN 2		
PREAD BASAL INSULIN + METFORMIN	0.76	0.3820
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
Dispersion		

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	3.2382	0.1931	16.77	<.0001	0.05	2.8596	3.6167	25.4869
2	3.8791	0.2228	17.41	<.0001	0.05	3.4424	4.3157	48.3793

TRTPN Least Squares Means

Planned Treatment (N)	Exponentiated Lower	Exponentiated Upper
1	17.4553	37.2140
2	31.2620	74.8691

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
1	2	-0.6409	0.2948	-2.17	0.0297	0.05	-1.2187	-0.06315

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)	Exponentiated	Exponentiated Lower	Exponentiated Upper
1	2	0.5268	0.2956	0.9388

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	IDegLira / IDeg	-0.6409	0.2948	-2.17	0.0297	0.05	-1.2187	-0.06315

Least Squares Means Estimate

Effect	Label	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	IDegLira / IDeg	0.5268	0.2956	0.9388

32: Hypoglycaemic episodes – treatment emergent – statistical sensitivity analysis – multiple imputation – full analysis set

Parameter Code=HYCNFSE Planned Treatment (N)=1 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.003123	0.035506	0.038632	152521

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.088058	0.080943	0.999919

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.271298	0.196551	2.886063	3.656534	152521	3.193123	3.464076

Parameter Estimates (1000 Imputations)

Parameter	t for H0:		
	Theta0	Parameter=Theta0	Pr > t
Estimate	0	16.64	<.0001

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

Parameter Code=HYCNFSE Planned Treatment (N)=2 Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSM_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.002588	0.048444	0.051034	387717

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.053475	0.050765	0.999949

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	3.880257	0.225908	3.437485	4.323030	387717	3.817666	4.255104

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0: Parameter=Theta0	Pr > t
Estimate	0	17.18	<.0001

Hypoglycaemic episodes - treatment emergent - statistical sensitivity analysis - multiple imputation - full analysis set

Parameter Code=HYCNFSE Label=IDegLira / IDeg Statement Number=1

The MIANALYZE Procedure

Model Information

Data Set WORK.LSME_MI
 Number of Imputations 1000

Variance Information (1000 Imputations)

Parameter	-----Variance-----			DF
	Between	Within	Total	
Estimate	0.005649	0.083893	0.089548	250504

Variance Information (1000 Imputations)

Parameter	Relative Increase in Variance	Fraction Missing Information	Relative Efficiency
Estimate	0.067407	0.063158	0.999937

Parameter Estimates (1000 Imputations)

Parameter	Estimate	Std Error	95% Confidence Limits		DF	Minimum	Maximum
Estimate	-0.608959	0.299246	-1.19547	-0.02244	250504	-1.010738	-0.360220

Parameter Estimates (1000 Imputations)

Parameter	Theta0	t for H0:	
		Parameter=Theta0	Pr > t
Estimate	0	-2.03	0.0419

33: 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	453
Number of Observations Used	452
Missing Values	1

Class Level Information

Class	Levels	Values
TRTPN	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Parameter Information

Parameter	Effect	TRTPN	PREAD
Prm1	Intercept		
Prm2	TRTPN	1	
Prm3	TRTPN	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD

Iteration History For Parameter Estimates

Iter	Ridge	Log		Prm1	Prm2	Prm4	Dispersion
		Likelihood					
0	0	-248.88659		4.7823425	-0.097818	0.0546535	0.8596882
1	1	-150.683		3.7018963	-0.473071	-0.076207	0.0626182
2	0.06	-144.39901		3.2524477	-0.570648	0.3099962	0.1619065
3	1	-143.90765		3.1384215	-0.614858	0.4166656	0.1781804
4	1	-143.75331		3.0873625	-0.619769	0.482044	0.1989049
5	1	-143.6442		3.0615369	-0.615829	0.514276	0.2241457
6	1	-143.53327		3.0479009	-0.611319	0.5296764	0.2550337
7	1	-143.40811		3.040686	-0.60782	0.5369217	0.2932181
8	1	-143.26397		3.0369288	-0.605294	0.5401102	0.3408479
9	1	-143.09875		3.0350577	-0.603396	0.541174	0.400609
10	0.06	-141.69204		3.0387866	-0.593892	0.5282424	2.4021374
11	0	-141.64987		3.0413466	-0.583393	0.5170532	2.0466411
12	0	-141.64952		3.0412361	-0.583948	0.5177205	2.0124952
13	0	-141.64952		3.041235	-0.583949	0.5177226	2.0121329
14	0	-141.64952		3.041235	-0.583949	0.5177226	2.0121329

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	449	161.6466	0.3600
Scaled Deviance	449	161.6466	0.3600
Pearson Chi-Square	449	487.6689	1.0861
Scaled Pearson X2	449	487.6689	1.0861
Log Likelihood		-141.6495	
Full Log Likelihood		-146.6193	
AIC (smaller is better)		301.2387	
AICC (smaller is better)		301.3281	

Hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYCNFSES

The GENMOD Procedure

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
BIC (smaller is better)		317.6934	

Last Evaluation Of The Negative Of The Gradient and Hessian

	Prm1	Prm2	Prm4	Dispersion
Gradient	-2.874E-9	-2.428E-9	-2.36E-10	2.4602E-8
Prm1	35.798234	19.712382	21.111393	-0.077305
Prm2	19.712382	19.712382	11.018598	-0.12625
Prm4	21.111393	11.018598	21.111393	0.0691198
Dispersion	-0.077305	-0.12625	0.0691198	0.5954467

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits
Intercept	1	3.0412	0.3284	2.3975 3.6850
TRTPN 1	1	-0.5839	0.3370	-1.2444 0.0765
TRTPN 2	0	0.0000	0.0000	0.0000 0.0000
PREAD BASAL INSULIN + METFORMIN	1	0.5177	0.3410	-0.1506 1.1861
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000 0.0000
Dispersion	1	2.0121	1.2985	0.5680 7.1278

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	85.74	<.0001
TRTPN 1	3.00	0.0831
TRTPN 2		
PREAD BASAL INSULIN + METFORMIN	2.31	0.1290
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
Dispersion		

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	2.7161	0.2263	12.00	<.0001	0.05	2.2726	3.1597	15.1219
2	3.3001	0.2531	13.04	<.0001	0.05	2.8041	3.7961	27.1153

TRTPN Least Squares Means

Planned Treatment (N)	Exponentiated Lower	Exponentiated Upper
1	9.7044	23.5640
2	16.5114	44.5290

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	2	-0.5839	0.3370	-1.73	0.0831	0.05	-1.2444	0.07654

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Exponentiated	Exponentiated Lower	Exponentiated Upper
1	2	0.5577	0.2881	1.0795

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	IDegLira / IDeg	-0.5839	0.3370	-1.73	0.0831	0.05	-1.2444	0.07654

Least Squares Means Estimate

Effect	Label	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	IDegLira / IDeg	0.5577	0.2881	1.0795

34: Nocturnal hypoglycaemic episodes – treatment emergent – supportive statistical analysis – full analysis set

Parameter Code=HYNOCSE

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	453
Number of Observations Used	452
Missing Values	1

Class Level Information

Class	Levels	Values
TRTPN	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Parameter Information

Parameter	Effect	TRTPN	PREAD
Prm1	Intercept		
Prm2	TRTPN	1	
Prm3	TRTPN	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD

Iteration History For Parameter Estimates

Iter	Ridge	Log		Prm1	Prm2	Prm4	Dispersion
		Likelihood					
0	0	-215.96192		4.6893282	-0.053017	0.0516002	0.8341748
1	16	-167.98527		4.4687164	-0.190605	-0.037648	0.8571859
2	1	-90.768506		3.5294783	-0.439246	-0.082759	0.170072
3	0.06	-72.013485		2.6019258	-0.475368	0.3715303	0.0162736
4	0.06	-67.946168		1.9188902	-0.540226	0.9677594	0.0165235
5	0.06	-67.192355		1.4811743	-0.565808	1.4152555	0.0170752
6	0.06	-67.124605		1.3101504	-0.563508	1.5891586	0.0177306
7	0.06	-67.122096		1.2752562	-0.559966	1.6240807	0.0184492
8	0.06	-67.121743		1.2704551	-0.559052	1.6287998	0.0192286
9	0.06	-67.121401		1.2698432	-0.558894	1.6293805	0.0200756
10	0.06	-67.121031		1.2697606	-0.558857	1.6294463	0.0209996
11	0.06	-67.120625		1.2697436	-0.558834	1.6294478	0.0220114
12	0.06	-67.120181		1.2697341	-0.558812	1.6294408	0.0231238
13	0.06	-67.119691		1.2697247	-0.558788	1.6294319	0.0243527
14	0.06	-67.11915		1.2697144	-0.55876	1.6294219	0.0257169
15	0.06	-67.118547		1.269703	-0.55873	1.6294107	0.0272398
16	0.06	-67.117872		1.2696902	-0.558696	1.6293982	0.0289502
17	0.06	-67.117112		1.2696757	-0.558658	1.629384	0.0308844
18	0.06	-67.116251		1.2696593	-0.558615	1.6293679	0.0330885
19	0.06	-67.115266		1.2696404	-0.558565	1.6293494	0.0356219
20	0.06	-67.11413		1.2696185	-0.558507	1.6293279	0.0385624
21	0.06	-67.112806		1.2695928	-0.558439	1.6293027	0.0420137
22	0.06	-67.111246		1.2695624	-0.558358	1.6292729	0.0461171
23	0.06	-67.109383		1.2695258	-0.558262	1.629237	0.0510694
24	0.06	-67.107124		1.269481	-0.558143	1.629193	0.0571518
25	0.06	-67.104336		1.269425	-0.557995	1.629138	0.0647792
26	0.06	-67.100824		1.2693535	-0.557805	1.6290678	0.0745844

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSSE

The GENMOD Procedure

Iteration History For Parameter Estimates

Iter	Ridge	Log Likelihood	Prm1	Prm2	Prm4	Dispersion
27	0.06	-67.096295	1.2692595	-0.557556	1.6289753	0.0875714
28	0.06	-67.090299	1.2691315	-0.557218	1.6288495	0.1054017
29	0.06	-67.08214	1.2689504	-0.556738	1.6286715	0.1309448
30	0.06	-67.070793	1.2686826	-0.556029	1.6284083	0.1693051
31	0.06	-67.055061	1.2682702	-0.554938	1.6280038	0.2293512
32	0.06	-67.034869	1.267629	-0.553245	1.6273782	0.3234446
33	0.06	-67.014505	1.2667097	-0.55083	1.6264928	0.4546296
34	0	-67.000492	1.2637589	-0.5432	1.6237742	1.0469637
35	0	-66.994046	1.2635923	-0.542893	1.623724	0.8558277
36	0	-66.993831	1.2637759	-0.543338	1.6238771	0.8174085
37	0	-66.99383	1.2637833	-0.543357	1.6238838	0.8156145
38	0	-66.99383	1.2637833	-0.543357	1.6238838	0.8156145

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	449	91.8805	0.2046
Scaled Deviance	449	91.8805	0.2046
Pearson Chi-Square	449	471.5693	1.0503
Scaled Pearson X2	449	471.5693	1.0503
Log Likelihood		-66.9938	
Full Log Likelihood		-67.6870	
AIC (smaller is better)		143.3740	
AICC (smaller is better)		143.4634	
BIC (smaller is better)		159.8287	

Last Evaluation Of The Negative Of The Gradient and Hessian

	Prm1	Prm2	Prm4	Dispersion
Gradient	7.2041E-8	-9.852E-8	8.936E-8	1.0772E-6
Prm1	16.193152	8.6776345	13.226628	0.0434796
Prm2	8.6776345	8.6776345	7.0138944	-0.053721
Prm4	13.226628	7.0138944	13.226628	0.0530582
Dispersion	0.0434796	-0.053721	0.0530582	0.272279

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	
Intercept		1.2638	0.6445	0.0005	2.5271
TRTPN 1	1	-0.5434	0.4998	-1.5229	0.4362
TRTPN 2	0	0.0000	0.0000	0.0000	0.0000

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Chi-Square	Pr > ChiSq
Intercept	3.84	0.0499
TRTPN 1	1.18	0.2769
TRTPN 2		

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSE

The GENMOD Procedure

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		DF	Estimate	Standard Error	Wald 95% Confidence Limits	
PREAD	BASAL INSULIN + METFORMIN	1	1.6239	0.6427	0.3642	2.8836
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
Dispersion		1	0.8156	1.9224	0.0080	82.7552

Analysis Of Maximum Likelihood Parameter Estimates

Parameter		Wald Chi-Square	Pr > ChiSq
PREAD	BASAL INSULIN + METFORMIN	6.38	0.0115
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		
Dispersion			

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	1.5324	0.3934	3.90	<.0001	0.05	0.7614	2.3033	4.6291
2	2.0757	0.4214	4.93	<.0001	0.05	1.2499	2.9016	7.9703

TRTPN Least Squares Means

Planned Treatment (N)	Exponentiated Lower	Exponentiated Upper
1	2.1413	10.0075
2	3.4899	18.2029

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
1	2	-0.5434	0.4998	-1.09	0.2769	0.05	-1.5229	0.4362

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Exponentiated	Exponentiated Lower	Exponentiated Upper
1	2	0.5808	0.2181	1.5468

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	IDegLira / IDeg	-0.5434	0.4998	-1.09	0.2769	0.05	-1.5229	0.4362

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSE

The GENMOD Procedure

Least Squares Means Estimate

Effect	Label	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	IDegLira / IDeg	0.5808	0.2181	1.5468

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	453
Number of Observations Used	452
Missing Values	1

Class Level Information

Class	Levels	Values
TRTPN	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Parameter Information

Parameter	Effect	TRTPN	PREAD
Prm1	Intercept		
Prm2	TRTPN	1	
Prm3	TRTPN	2	
Prm4	PREAD		BASAL INSULIN + METFORMIN
Prm5	PREAD		BASAL INSULIN + METFORMIN + ONE OTHER OAD

Iteration History For Parameter Estimates

Iter	Ridge	Log Likelihood	Prm1	Prm2	Prm4	Dispersion
0	0	-212.11027	4.6898332	-0.053761	0.038275	0.8351092
1	16	-162.95238	4.4666039	-0.193	-0.053776	0.8590154
2	1	-81.103474	3.4686626	-0.455285	-0.129406	0.125644
3	0.06	-63.352907	2.6085205	-0.526344	0.230995	0.0522172
4	0.06	-59.275366	1.9430772	-0.623397	0.7585306	0.0580303
5	0.06	-58.55622	1.5250015	-0.677486	1.1872585	0.073142
6	0.06	-58.483218	1.3669014	-0.682462	1.35142	0.1028472
7	0.06	-58.448149	1.3378943	-0.67888	1.3802064	0.17162
8	0.06	-58.351696	1.3337319	-0.675113	1.3819333	0.421137
9	0.06	-58.185224	1.3299425	-0.662876	1.3760787	1.7256941
10	0	-58.184617	1.3257512	-0.649048	1.3695915	1.7974982
11	0	-58.184617	1.3256893	-0.648998	1.3695947	1.7956447
12	0	-58.184617	1.3256893	-0.648998	1.3695947	1.7956447

Criteria For Assessing Goodness Of Fit

Criterion	DF	Value	Value/DF
Deviance	449	74.9894	0.1670
Scaled Deviance	449	74.9894	0.1670
Pearson Chi-Square	449	474.3927	1.0566
Scaled Pearson X2	449	474.3927	1.0566
Log Likelihood		-58.1846	
Full Log Likelihood		-58.8778	
AIC (smaller is better)		125.7555	
AICC (smaller is better)		125.8450	
BIC (smaller is better)		142.2103	

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	-9.349E-9	-3.309E-8	3.9818E-9	1.6756E-7
Prm1	12.891925	6.6108821	9.9666887	0.0342268
Prm2	6.6108821	6.6108821	5.0193772	-0.037243
Prm4	9.9666887	5.0193772	9.9666887	0.0460269
Dispersion	0.0342268	-0.037243	0.0460269	0.1113227

Algorithm converged.

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	DF	Estimate	Standard Error	Wald 95% Confidence Limits	
Intercept	1	1.3257	0.6589	0.0343	2.6170
TRTPN 1	1	-0.6490	0.5598	-1.7462	0.4482
TRTPN 2	0	0.0000	0.0000	0.0000	0.0000
PREAD BASAL INSULIN + METFORMIN	1	1.3696	0.6658	0.0647	2.6745
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD	0	0.0000	0.0000	0.0000	0.0000
Dispersion	1	1.7956	3.0130	0.0670	48.1374

Analysis Of Maximum Likelihood Parameter Estimates

Parameter	Wald Chi-Square	Pr > ChiSq
Intercept	4.05	0.0442
TRTPN 1	1.34	0.2463
TRTPN 2		
PREAD BASAL INSULIN + METFORMIN	4.23	0.0397
PREAD BASAL INSULIN + METFORMIN + ONE OTHER OAD		
Dispersion		

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	1.3615	0.4261	3.20	0.0014	0.05	0.5264	2.1966	3.9020
2	2.0105	0.4434	4.53	<.0001	0.05	1.1415	2.8795	7.4670

TRTPN Least Squares Means

Planned Treatment (N)	Exponentiated Lower	Exponentiated Upper
1	1.6927	8.9946
2	3.1314	17.8055

Nocturnal hypoglycaemic episodes - treatment emergent - supportive statistical analysis - full analysis set

Parameter Code=HYNOCSES

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	-0.6490	0.5598	-1.16	0.2463	0.05	-1.7462	0.4482

Differences of TRTPN Least Squares Means

Planned Treatment (N)	Planned Treatment (N)	Exponentiated	Exponentiated Lower	Exponentiated Upper
1	2	0.5226	0.1744	1.5655

Least Squares Means Estimate

Effect	Label	Estimate	Standard Error	z Value	Pr > z	Alpha	Lower	Upper
TRTPN	IDegLira / IDeg	-0.6490	0.5598	-1.16	0.2463	0.05	-1.7462	0.4482

Least Squares Means Estimate

Effect	Label	Exponentiated	Exponentiated Lower	Exponentiated Upper
TRTPN	IDegLira / IDeg	0.5226	0.1744	1.5655

35: Pulse after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	65.0379

Fit Statistics

-2 Res Log Likelihood	3174.8
AIC (Smaller is Better)	3176.8
AICC (Smaller is Better)	3176.9
BIC (Smaller is Better)	3180.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	39.2829	3.1653	449	12.41
trtpn		1	4.4149	0.8040	449	5.49
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2566	0.7591	449	-0.34
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.5115	0.03986	449	12.83

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

Parameter Code=C49676X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.7355	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			33.0623	45.5036
trtpn		1	2.8348	5.9950
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-1.7485	1.2352
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.4332	0.5898

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	30.15	<.0001
PREAD	1	449	0.11	0.7355
BASE	1	449	164.70	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	83.1604	0.4641	449	179.18	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	78.7455	0.6564	449	119.97	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	82.2483	84.0725	1.306E36	5.248E35	3.252E36
trtpn	LSMeans, IDeg	77.4555	80.0355	1.58E34	4.35E33	5.741E34

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	4.4149	0.8040	449	5.49

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

Parameter Code=C49676X

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	<.0001	0.05	2.8348	5.9950	82.6739

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	17.0278	401.40

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

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	65.0379

Fit Statistics

-2 Res Log Likelihood	3174.8
AIC (Smaller is Better)	3176.8
AICC (Smaller is Better)	3176.9
BIC (Smaller is Better)	3180.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	39.2829	3.1653	449	12.41
trtpn		1	4.4149	0.8040	449	5.49
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		-0.2566	0.7591	449	-0.34
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.4885	0.03986	449	-12.26

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

Parameter Code=C49676X

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	<.0001	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.7355	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			33.0623	45.5036
trtpn		1	2.8348	5.9950
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-1.7485	1.2352
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.5668	-0.4102

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	30.15	<.0001
PREAD	1	449	0.11	0.7355
BASE	1	449	150.22	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	5.7719	0.4641	449	12.44	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	1.3570	0.6564	449	2.07	0.0393

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	4.8598	6.6839
trtpn	Change from baseline, IDeg	0.05	0.06695	2.6470

36: Systolic blood pressure after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	125.53

Fit Statistics

-2 Res Log Likelihood 3470.8
 AIC (Smaller is Better) 3472.8
 AICC (Smaller is Better) 3472.9
 BIC (Smaller is Better) 3476.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	64.3085	4.9405	449	13.02
trtpn		1	-3.1299	1.1171	449	-2.80
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		1.2168	1.0553	449	1.15
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.4942	0.03775	449	13.09

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=SYSBPMEA

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0053	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.2495	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			54.5991	74.0178
trtpn		1	-5.3252	-0.9345
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.8572	3.2909
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.4200	0.5684

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	7.85	0.0053
PREAD	1	449	1.33	0.2495
BASE	1	449	171.34	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	125.38	0.6448	449	194.45	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	128.51	0.9120	449	140.92	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	124.11	126.65	2.834E54	7.981E53	1.006E55
trtpn	LSMeans, IDeg	126.72	130.30	6.482E55	1.08E55	3.891E56

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	-3.1299	1.1171	449	-2.80

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=SYSBPMEA

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.0053	0.05	-5.3252	-0.9345	0.04372

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.004867	0.3928

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=SYSPMEA

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	125.53

Fit Statistics

-2 Res Log Likelihood 3470.8
 AIC (Smaller is Better) 3472.8
 AICC (Smaller is Better) 3472.9
 BIC (Smaller is Better) 3476.9

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	64.3085	4.9405	449	13.02
trtpn		1	-3.1299	1.1171	449	-2.80
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		1.2168	1.0553	449	1.15
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.5058	0.03775	449	-13.40

Systolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=SYSBPMEA

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.0053	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.2495	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			54.5991	74.0178
trtpn		1	-5.3252	-0.9345
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.8572	3.2909
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.5800	-0.4316

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	7.85	0.0053
PREAD	1	449	1.33	0.2495
BASE	1	449	179.51	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	-3.3685	0.6448	449	-5.22	<.0001
trtpn	Change from baseline, IDeg	WORK.ADATA2	-0.2387	0.9120	449	-0.26	0.7937

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-4.6357	-2.1014
trtpn	Change from baseline, IDeg	0.05	-2.0309	1.5536

37: Diastolic blood pressure after 26 weeks of treatment – change from baseline – supportive statistical analysis – full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters 1
 Columns in X 6
 Columns in Z 0
 Subjects 1
 Max Obs per Subject 453

Number of Observations

Number of Observations Read 453
 Number of Observations Used 453
 Number of Observations Not Used 0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	49.8665

Fit Statistics

-2 Res Log Likelihood 3055.4
 AIC (Smaller is Better) 3057.4
 AICC (Smaller is Better) 3057.4
 BIC (Smaller is Better) 3061.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period	Estimate	Standard Error	DF	t Value
Intercept		01 (N)	31.4557	3.1010	449	10.14
trtpn		1	0.3195	0.7041	449	0.45
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		1.0538	0.6650	449	1.58
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			0.5940	0.03829	449	15.51

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=DIABPMEA

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.6502	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1137	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			25.3613	37.5500
trtpn		1	-1.0642	1.7031
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.2530	2.3606
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			0.5188	0.6693

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	0.21	0.6502
PREAD	1	449	2.51	0.1137
BASE	1	449	240.63	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t	Alpha
trtpn	LSMeans, IDegLira	WORK.ADATA2	79.3361	0.4064	449	195.22	<.0001	0.05
trtpn	LSMeans, IDeg	WORK.ADATA2	79.0166	0.5748	449	137.47	<.0001	0.05

Least Squares Means Estimates

Effect	Label	Lower	Upper	Exponentiated	Exponentiated Lower	Exponentiated Upper
trtpn	LSMeans, IDegLira	78.5374	80.1347	2.852E34	1.283E34	6.34E34
trtpn	LSMeans, IDeg	77.8870	80.1462	2.072E34	6.697E33	6.413E34

Least Squares Means Estimate

Effect	Label	Margins	Estimate	Standard Error	DF	t Value
trtpn	Treatment contrast, IDegLira - IDeg	WORK.ADATA2	0.3195	0.7041	449	0.45

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive
statistical analysis - full analysis set - appendix

Parameter Code=DIABPMEA

The Mixed Procedure

Least Squares Means Estimate

Effect	Label	Pr > t	Alpha	Lower	Upper	Exponentiated
trtpn	Treatment contrast, IDegLira - IDeg	0.6502	0.05	-1.0642	1.7031	1.3764

Least Squares Means Estimate

Effect	Label	Exponentiated Lower	Exponentiated Upper
trtpn	Treatment contrast, IDegLira - IDeg	0.3450	5.4912

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

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	2	1 2
PREAD	2	BASAL INSULIN + METFORMIN BASAL INSULIN + METFORMIN + ONE OTHER OAD

Dimensions

Covariance Parameters	1
Columns in X	6
Columns in Z	0
Subjects	1
Max Obs per Subject	453

Number of Observations

Number of Observations Read	453
Number of Observations Used	453
Number of Observations Not Used	0

Covariance Parameter Estimates

Cov Parm	Estimate
Residual	49.8665

Fit Statistics

-2 Res Log Likelihood	3055.4
AIC (Smaller is Better)	3057.4
AICC (Smaller is Better)	3057.4
BIC (Smaller is Better)	3061.5

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Estimate	Standard Error	DF	t Value
Intercept			31.4557	3.1010	449	10.14
trtpn		1	0.3195	0.7041	449	0.45
trtpn		2	0			
PREAD	BASAL INSULIN + METFORMIN		1.0538	0.6650	449	1.58
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD		0			
BASE			-0.4060	0.03829	449	-10.60

Diastolic blood pressure after 26 weeks of treatment - change from baseline - supportive statistical analysis - full analysis set - appendix

Parameter Code=DIABPMEA

The Mixed Procedure

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Pr > t	Alpha
Intercept			<.0001	0.05
trtpn		1	0.6502	0.05
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		0.1137	0.05
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			<.0001	0.05

Solution for Fixed Effects

Effect	Pre Trial anti-Diabetic treatment	Planned Treatment for Period 01 (N)	Lower	Upper
Intercept			25.3613	37.5500
trtpn		1	-1.0642	1.7031
trtpn		2		
PREAD	BASAL INSULIN + METFORMIN		-0.2530	2.3606
PREAD	BASAL INSULIN + METFORMIN + ONE OTHER OAD			
BASE			-0.4812	-0.3307

Type 3 Tests of Fixed Effects

Effect	Num DF	Den DF	F Value	Pr > F
trtpn	1	449	0.21	0.6502
PREAD	1	449	2.51	0.1137
BASE	1	449	112.39	<.0001

Least Squares Means Estimates

Effect	Label	Margins	Estimate	Standard Error	DF	t Value	Pr > t
trtpn	Change from baseline, IDegLira	WORK.ADATA2	0.1124	0.4064	449	0.28	0.7823
trtpn	Change from baseline, IDeg	WORK.ADATA2	-0.2071	0.5748	449	-0.36	0.7188

Least Squares Means Estimates

Effect	Label	Alpha	Lower	Upper
trtpn	Change from baseline, IDegLira	0.05	-0.6863	0.9111
trtpn	Change from baseline, IDeg	0.05	-1.3367	0.9225