COVER LETTER

To
Clinical Trials PRS Registration System
Dated: 08/06/2023

Subject: Submission of a project termed **"**Comparison of real-time CGMS with intermittently scanned CGMS in adolescents and adults with Type 1 Diabetes Mellitus: An Open Label Randomised Control Cross Over Study"

Dear sir/madam;

This is to certify that I'm hereby submitting a project entitled "Comparison of real-time CGMS with intermittently scanned CGMS in adolescents and adults with Type 1 Diabetes Mellitus: An Open Label Randomised Control Cross Over Study"for registration.

Regards
Dr Sanjay Kumar Bhadada

PLAN OF PROJECT

COMPARISON OF REAL-TIME CGMS WITH INTERMITTENTLY SCANNED CGMS IN ADOLESCENTS AND ADULTS WITH TYPE 1 DIABETES MELLITUS: AN OPEN LABEL RANDOMISED CONTROL CROSS OVER STUDY

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LIST OF ABBREVATIONS

ABF	After Breakfast Plasma Glucose
ADN	After Dinner Plasma Glucose
AGE	Advanced Glycation End product
ALN	After lunch plasma glucose
aOR	Adjusted Odds ratio
ANOVA	Analysis of variance
BDN	Before Dinner Plasma Glucose
BMI	Body Mass Index
BLN	Before Lunch Plasma Glucose
CGM(S)	Continuous Glucose Monitoring (System)
CI	Confidence interval
CSII	Continuous Subcutaneous Insulin Infusion
ECLIA	Electro Chemi Luminescence immuno assay
DR	Diabetic Retinopathy
eGFR	Estimated glomerular filtration rate
FGM	Flash Glucose Monitoring
FPG	Fasting plasma glucose
FSLP	Free Style Libre Pro
HbA1c	Glycated hemoglobin
IAH	Impaired Awareness of Hypoglycemia

ICR	Insulin Carbohydrate Ratio
ISF	Insulin Sensitivity Factor
IgA-tTG	Tissue transglutaminase
is-CGM(S)	Intermittently scanned CGM(S)
LADA	Latent autoimmune diabetes of adulthood
LH	Luteinising hormone
MSI	Multiple Subcutaneous Injections
OGTT	Oral glucose tolerance test
PPPG	Post prandial plasma glucose
RCT	Randomized control trial
Rt-CGM(S)	Real time continuous Glucose Monitoring (System)
SMBG	Self Monitoring of Blood Glucose
T1D	Type 1 diabetes mellitus
T2D	Type 2 diabetes mellitus
ULN	Upper limit of Normal

INTRODUCTION

Type 1 diabetes accounts for 10–15% of the worldwide diabetes prevalence and its incidence is increasing worldwide by 3–5%percent annually (1). Optimal glycaemic control is inevitable to prevent microvascular and macrovascular complications of the disease, however patients on intensive control regimes are at risk for hypoglycaemia (2,3,4).

Glucose measurements are critically important for effective diabetes control. Currently, measurements performed by patients from capillary blood (self-monitoring of blood glucose, SMBG) are the golden standard of routine care (5). It has been demonstrated that frequent testing regimes improve glycaemic control (6,7) however, increasing the number of finger pricking above a certain threshold might yield no additional benefits but reflect badly on patient's quality of life (8).

However, SMBG only provides information about a single time-point, it does not accurately reflect the glycaemic variability and often is painful and cumbersome.

Only approximately 30% of individuals with type 1 diabetes meet the American Diabetes Association goal of hemoglobin A1c (HbA1c) level of 7.5% (58 mmol/mol) for children (<18 years) and 7.0% (53 mmol/mol) for adults (≥18 years), (9) indicating the need for better approaches to diabetes management, CGMS represents such an approach. CGMS systems measure glucose in the interstitial fluid and are currently divided into real-time continuous systems (rt-CGMS) and intermittently scanned systems (is-CGMS). These systems allow a semi-continuous insight, not only in glucose concentrations, but also in trends in time. Rt-CGM systems automatically transmit data to the receiver and/or smartphone, whereas is-CGM systems require a

person to "swipe" the receiver and/or smartphone close to the sensor to obtain current and historical sensor glucose data. A key differentiator between these technologies was the added safeguard of active alarms/alerts. New is-CGM systems offer optional alerts that warn users when glucose levels fall below or rise above the programmed threshold; however, the current iteration of these technologies do not warn users of predicted low or high glucose levels. Both rt-CGM and is-CGM technologies are available as standalone devices. Some of the indications for continuous glucose monitoring in adults with Type 1 DM are as follows (10):

- All persons with diabetes treated with intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump
- All individuals with problematic hypoglycaemia (frequent/severe hypoglycaemia, nocturnal hypoglycaemia, hypoglycaemia unawareness).
- Children/adolescents with T1D.
- Pregnant women with T1D and T2D treated with intensive insulin therapy.

Other indications:

- Women with gestational diabetes mellitus (GDM) on insulin therapy.
- Adults undergoing change in their diabetes regimen.
- Postprandial hyperglycaemia.
- Patients with discrepancies between HbA1c and SMBG.
- Patients unable to achieve goal with SMBG

Currently following CGM systems are available in India:

- Free Style Libre pro
- Free Style Libre
- Dexcom G6 platinum
- Medtronic’s Guardian Connect

Key differences between is-CGMS (FSLP) and rt-CGMS(Medtronic Guardian 3) are as follows:

	Abbott Libre (FSLP)	**Medtronic Guardian 3**
Age(FDA approved)	≥18yrs	≥2yrs
rt-CGM or is-CGM	is-CGM	rt-CGM
Surgically implanted	No	No
Sensor life	14days	7-10days
BG readings	Every 15mins	Every 5 mins
Alarms/alerts	No	Yes
Ability to share	Yes	Indirectly
Warm up	1 hour	Less than 2 hours

Use of CGM is associated with a reduction in HbA1c (11), and reduced exposure to, and risk of hypoglycaemia (12) in people using insulin pump and multiple-dose injection regimens (13). The impact on glucose and hypoglycaemia outcomes has additionally been confirmed in people with Type 1 diabetes and impaired hypoglycaemia awareness (14).

Superiority of rt-CGMS in comparison to SMBG for glycaemic control and reduction of number of hypoglycaemic events is clearly established in multiple RCTs (15,16,17,18,19). Many studies comparing is-CGM with SMBG are also available.

Large randomized controlled trials using flash CGM have demonstrated significant improvements in hypoglycaemia, glycaemic variability, and patient satisfaction in individuals with well-controlled T1D (20) and T2D (21) who were treated with intensive insulin therapy. Improvements in glycated haemoglobin A1c (HbA1c) and percentage of time within the target glucose range were observed in T1D (20) but not

T2D (21) patients. Moreover, recent real-world observational studies have reported significant reductions in hospital admissions for severe hypoglycaemia and/or diabetic ketoacidosis in large cohorts of T1D adults who used flash CGM for 12 months (22,23). However, studies comparing rt-CGMS vs is-CGMS in adult T1D patients are scarce. Rt-CGMS has been shown to be better compared to is-CGMS especially in patients with impaired hypoglycaemic awareness (24,25) but in patients with normal hypoglycaemic awareness it is not proven. A recent study published in 2020 included adults with type 1 diabetes (T1D) and normal hypoglycaemia awareness (Gold score <4) comparing rt-CGM (Guardian Connect Mobile) or is-CGM (Free Style Libre) in exercise phase and in the home phase revealed that rt-CGM was superior to is-CGM in reducing hypoglycaemia and improving time in range in adults with T1D with normal hypoglycaemia awareness (26).

However, it had many limitations like:

1. Short duration: Study duration was 4 weeks only so it could not assess the effect on long term glycemic control in term of HbA1C reduction
2. Cross over between rtCGM and isCGM was not done.
3. CGM was worn continuously for 4 days in exercise phase and 4 weeks for home phase which is not practical in a resource constraint setting.

Hence, there arises a need for more studies comparing rt-CGMS and is-CGMS in resource constraint settings like ours.

REVIEW OF LITERATURE

CGMS (rt-CGMS and is-CGMS) vs SMBG in T1D

There are various studies comparing CGMS mostly rt-CGMS with SMBG in T1D patients, some of which are as follows:

IMPACT study (20)	239 T1D pt with Hba1c 6.9% at baseline	Use of is-CGM is a/w 38% reduction in time spent in hypoglycemia(<70)
DIAMOND trial (15)	158 T1D with HbA1c 7.5-9.9% on MSI, rt-CGM compared to SMBG	Lower HbA1c(-1% vs 0.4%, p<0.001) at 24 weeks TBR(-22min vs 37min, p=0.002) TAR(-78 vs 78mins, p<0.001)
GOLD study (27)	6months cross over, 142 adult T1D patients CGMS vs conventional on HbA1c at 26 weeks	HbA1c was 7.92%(63 mmol/mol) during CGMS and 8.35%(68 mmol/mol) during conventional (mean difference,−0.43%[95%CI, −0.57%to −0.29%] or −4.7 [−6.3 to −3.1 mmol/mol]; P < .001)
HypoDE study (16)	141 T1D pts, number of hypoglycemic events in follow up phase(22-26)weeks were compared in rt-CGM vs SMBG	No. of hypoglycemic events in rt-CGM decreased from 10.4 to 3.4% whereas in control 13.5 to 13.2%

GOLD - 3(28)	rt-CGM vs SMBG, 161 T1D patients over a period of 69 weeks, duration of episodes of nocturnal hypoglycemia	Decrease in nocturnal hypoglycemia <70-19.6 to 10.2min <54-8.9 to 3.1 min Daytime hypoglycemia 49 to 29min/d
RESCUE study(29)	rt-CGM vs SMBG in 441 T1D patients over 24 months	Significant reductions in no. of hypoglycaemia and DKA hospitalization
Meta-analysis of RCTs Dicembrini etal(30)	Meta-analysis of RCTs comparing CGMS vs SMBG in T1D patients	CGM was associated with a significantly lower HbA1c at endpoint in comparison with SMBG (− 0.24 [− 0.34,− 0.13]%); and a significantly lower risk of severe hypoglycemia than SMBG.

Bolinder etal conducted a multicentre, prospective, non-masked, randomised controlled trial(20), with adult patients with well controlled type 1 diabetes (HbA1c ≤58 mmol/mol [7·5%]) from 23 European diabetes centres in which all participants wore the blinded sensor for 2 weeks and, those with readings for at least 50% of the period were randomly assigned (1:1) to flash sensor-based glucose monitoring (intervention group) or to self-monitoring of blood glucose with capillary strips (control group).The primary outcome was change in time in hypoglycaemia (<3·9 mmol/L [70 mg/dL]) between baseline and 6 months in the full analysis set. Between Sept 4, 2014, and Feb 12, 2015, 120 participants were randomly assigned to the intervention group and 121 to the control group. They found mean time in hypoglycaemia changed from 3·38 h/day

at baseline to 2·03 h/day at 6 months (baseline adjusted mean change −1·39) in the intervention group, and from 3·44 h/day to 3·27 h/day in the control group (−0·14); with the between-group diff erence of −1·24 (SE 0·239; p<0·0001), equating to a 38% reduction in time in hypoglycaemia in the intervention group and no device-related hypoglycaemia or safety issues.13 adverse events were reported by ten participants related to the sensor—four of allergy events (one severe, three moderate); one itching (mild); one rash (mild); four insertion-site symptom (severe); two erythema (one severe, one mild); and one oedema (moderate). They concluded Novel flash glucose is-CGMS reduced the time adults with well controlled type 1 diabetes spent in hypoglycaemia.

Beck etal conducted a Randomized clinical trial conducted between October 2014 and May 2016 at 24 endocrinology practices in the United States that included 158 adults with type 1 diabetes who were using multiple daily insulin injections and had hemoglobin A1c (HbA1c) levels of 7.5%to 9.9%.Random assignment 2:1 toCGM(n = 105) or usual care (control group; n = 53) was done in this study and the difference in change in central-laboratory–measured HbA1c level was compared from baseline to 24 weeks. Also, secondary outcome as duration of hypoglycemia at less than 70mg/dL, measured with CGM for 7 days at 12 and 24 weeks was reported. It was found that mean HbA1c reduction from baseline was 1.1%at 12 weeks and 1.0% at 24 weeks in the CGM group and 0.5% and 0.4%, respectively, in the control group (repeated-measures model P < .001). At 24 weeks, the adjusted treatment-group difference in mean change in HbA1c level from baseline was –0.6%(95%CI, –0.8%to –0.3%; P < .001) and median duration of hypoglycemia at less than <70mg/dL was 43 min/d (IQR, 27-69) in the CGM group vs 80 min/d (IQR, 36-111) in the control group (P = .002). Severe hypoglycemia events occurred in 2 participants in each group. This trial

revealed that among adults with type 1 diabetes who used multiple daily insulin injections, the use of CGM compared with usual care resulted in a greater decrease in HbA1c level during 24 weeks.

Lind etal conducted an open-label crossover randomized clinical trial conducted in 15 diabetes outpatient clinics in Sweden between February 24, 2014, and June 1, 2016 that included 161 individuals with type 1 diabetes and hemoglobin A1c (HbA1c) of at least 7.5%(58 mmol/mol) treated with MSIs in which participants were randomized to receive treatment using a CGMS or conventional treatment for 26 weeks, separated by a washout period of 17 weeks and compared the difference in HbA1c between weeks 26 and 69 for the 2 treatments and also studied adverse events including severe hypoglycemia. In this trial, 161 (45.3% women) randomized participants with a mean age was 43.7 years, with mean HbA1c was 8.6%(70 mmol/mol) but only 142 participants had follow-up data in both treatment periods. It was found that mean HbA1c was 7.92% (63 mmol/mol) during continuous glucose monitoring use and 8.35%(68 mmol/mol) during conventional treatment (mean difference,−0.43%[95%CI, −0.57%to −0.29%] or −4.7 [−6.3 to −3.1 mmol/mol]; P < .001). Five patients in the conventional treatment group and 1 patient in the continuous glucose monitoring group had severe hypoglycemia. The trial revealed that among patients with inadequately controlled type 1 diabetes treated with MSIs , the use of continuous glucose monitoring compared with conventional treatment for 26 weeks resulted in lower HbA1c.

Heinemann etal conducted the HypoDE study which was a 6-month, multicentre, open-label, parallel, randomised controlled trial done at 12 diabetes practices in Germany in which eligible participants had type 1 diabetes and a history of impaired hypoglycaemia awareness or severe hypoglycaemia during the previous year, all participants wore a masked rtCGM system for 28 days and were then randomly

assigned to 26 weeks of unmasked rtCGM (Dexcom G5 Mobile system) or to the control group (continuing with SMBG). Block randomisation with 1:1 allocation was done centrally and control participants wore a masked rtCGM system during the follow-up phase (weeks 22-26). The primary outcome was the baseline-adjusted number of hypoglycaemic events (defined as glucose ≤3·0 mmol/L for ≥20 min) during the follow-up phase. In the study, 149 participants were randomly assigned (n=74 to the control group; n=75 to the rtCGM group) and 141 completed the follow-up phase (n=66 in the control group, n=75 in the rtCGM group). The mean number of hypoglycaemic events per 28 days among participants in the rtCGM group was reduced from 10·8 (SD 10·0) to 3·5 (4·7); reductions among control participants were negligible (from 14·4 [12·4] to 13·7 [11·6]). Incidence of hypoglycaemic events decreased by 72% for participants in the rtCGM group (incidence rate ratio 0·28 [95% CI 0·20-0·39], p<0·0001), thus CGMS reduced number of hypoglycemic events in T1D (16).

Ólafsdóttir etal performed evaluations from the GOLD randomized trial, an open-label multicenter crossover randomized clinical trial (n = 161) over 69 weeks comparing CGM to SMBG in persons with T1D treated with MSI and they used masked CGM and the hypoglycemia confidence questionnaire for evaluations. It was found that time with nocturnal hypoglycemia, glucose levels <70 mg/dL was reduced by 48% (10.2 vs. 19.6 min each night, P < 0.001) and glucose levels <54 mg/dL by 65%. (3.1 vs. 8.9 min, P < 0.001). For the corresponding glucose cutoffs, daytime hypoglycemia was reduced by 40% (29 vs. 49 min, P < 0.001) and 54% (8 vs. 18 min., P < 0.001), respectively. Compared with SMBG, CGM use improved hypoglycemia-related confidence in social situations (P = 0.016) and confidence in more broadly avoiding serious problems due to hypoglycemia (P = 0.0020). Persons also reported greater confidence in detecting and responding to decreasing blood glucose levels (thereby avoiding hypoglycemia)

during CGM use (P = 0.0033) and indicated greater conviction that they could more freely live their lives despite the risk of hypoglycemia (P = 0.022). Hence, CGM reduced time in both nocturnal and daytime hypoglycemia in persons with T1D treated with MSI and improved hypoglycemia-related confidence, especially in social situations, thus contributing to greater well-being and quality of life(28).

Charleer etal conducted a 24-month, prospective, observational cohort study which followed 441 adults with insulin pumps receiving full reimbursement for rtCGM and 42% had IAH. The primary end point was evolution of HbA1c, with secondary end points change in acute hypoglycemia complications, diabetes-related work absenteeism, and quality of life scores. Additionally, they evaluated whether people could achieve glycemic consensus targets during follow-up. It was found that after 24 months, HbA1c remained significantly lower compared with baseline (7.64% [60 mmol/mol] vs. 7.37% [57 mmol/mol], P < 0.0001) and sustained benefits were also observed for the score on the hypoglycemia fear survey and hypoglycemia-related acute complications irrespective of hypoglycemia awareness level. Moreover, people with IAH had the strongest improvement, especially for severe hypoglycemia (862 events in the year before vs. 119 events per 100 patient-years in the 2nd year, P < 0.0001) and over 24 months, more people were able to meet hypoglycemia consensus targets at the expense of slightly fewer people achieving hyperglycemia consensus targets. Furthermore, the number of people with HbA1c <7% (<53 mmol/mol) without severe hypoglycemia events more than doubled (11.0% vs. 25.4%, P < 0.0001). Thus, use of rtCGM led to sustained improvements in hypoglycemia-related glucose control over 24 months and lower fear of hypoglycemia, fewer acute hypoglycemia-related events, and fewer diabetes-related days off from work were observed, particularly in those with IAH(29).

Dicembrini etal conducted analysis of RCTs comparing CGM or FGM with SMBG, with a duration of at least 12 weeks. The principal endpoint was HbA1c at the end of the trial and a secondary endpoint was severe hypoglycemia. Mean and 95% confidence intervals for HbA1c and Mantel–Haenzel odds ratio [MH-OR] for severe hypoglycemia were calculated, using random effect models and a sensitivity analysis was also performed using fixed effect models. In addition, the following secondary endpoints were explored, using the same methods: time in range, health-related quality of life, and treatment satisfaction. Separate analyses were performed for trials comparing CGM with SMBG, and those comparing CGM + CSII and SMBG + MSI. It was found that CGM was associated with a significantly lower HbA1c at endpoint in comparison with SMBG (− 0.24 [− 0.34,− 0.13]%); and a significantly lower risk of severe hypoglycemia than SMBG, treatment satisfaction and quality of life were not measured, or not reported, in the majority of studies and FGM showed a significant reduction in the incidence of mild hypoglycemia and an increased treatment satisfaction, but no significant results are shown in HbA1c. Also, CGM + CSII in comparison with SMBG + MSI was associated with a significant reduction in HbA1c. Thus, CGMS compared to SMBG has showed a reduction in HbA1c and severe hypoglycemia in patient with type 1 diabetes and even greater reduction in HbA1c with CGMS + CSII than with SMBG(30).

From above studies we conclude that CGMS is better than SMBG in T1D patients with regards to improvement in HbA1c and decrease in number of hypoglycemic events.

Rt-CGMS vs is-CGMS in T1D

There are very few studies comparing rt-CGMS vs is-CGMS in T1D patients some of which are as follows:

Reddy et al(2017) (31)	40adults T1DM with problematic hypoglycemia	Improvement in time spent in hypoglycemia with rtCGM compared to isCGM
IHART-CGM extension (2018) (32)	rtCGM vs isCGM in 40 T1D after 8 and 16 weeks , switching from is-CMS to rt-CGM	Significant reduction in percentage time in hypoglycemia (<3.0 mmol/L) in the group switching from flash to rt-CGMS (from 5.0 [3.7–8.6]% to 0.8 [0.4–1.9]%, P = 0.0001), and time in target range (3.9–10 mmol/L) increased in the flash group after switching to rt-CGMS (60.0 [54.5–67.8] vs. 67.4 [56.3–72.4], P = 0.02) No reduction in TBR with isCGMS (11.9% baseline to 11.9% at 8 weeks) compared to rtCGMS (8.8% to 6.2%).
CORRIDA RCT (2020) (26)	rtCGMS vs isCGMS, 60 T1DM	Time in Hypoglycemia during exercise was lower in rtCGM(6.8% vs 11.4%, p=0.018)& during home phase(5.3% vs 7.3%,p=0.035).

Reddy etal assessed the impact of CGMS and FGM in a high-risk group of people with T1D by a randomized, non-masked parallel group study using a multiple-dose insulin-injection regimen with inclusion of patients with a Gold score of ≥ 4 or recent severe hypoglycaemia. Following 2 weeks of blinded CGM, they were randomly assigned 40

T1D patients to CGM (Dexcom G5) or flash glucose monitoring (Abbott Freestyle Libre) for 8 weeks. The primary outcome was the difference in time spent in hypoglycaemia (below 3.3 mmol/l) from baseline to endpoint with CGM versus flash glucose monitoring. In this trial, 40 participants were randomized to CGM (n = 20) or flash glucose monitoring (n = 20), the participants (24 men, 16 women) had a median (IQR) age of 49.6 (37.5–63.5) years, duration of diabetes of 30.0 (21.0–36.5) years and HbA1c of 56 (48–63) mmol/mol [7.3 (6.5–7.8)%].The baseline median percentage time < 3.3 mmol/l was 4.5% in the CGM group and 6.7% in the flash glucose monitoring. At the end-point, the percentage time < 3.3 mmol/l was 2.4%, and 6.8% respectively (median between group difference -4.3%, P = 0.006) hence the time spent in hypoglycaemia at all thresholds, and hypoglycaemia fear, were different between groups, favouring CGM. They concluded that CGM more effectively reduces time spent in hypoglycaemia in people with Type 1 diabetes and impaired awareness of hypoglycaemia compared with flash glucose monitoring.

The I HART CGM study showed that real-time continuous glucose monitoring (RT-CGM) has greater beneficial impact on hypoglycemia than intermittent flash glucose monitoring (flash) in adults with type1 diabetes (T1D) at high risk. Reddy etal then evaluated the impact of continuing RT-CGM or switching from flash to RT-CGM for another 8 weeks as an extension of I HART CGM study. It was a prospective randomized parallel group study with an extension phase, there was a 2-week run-in with blinded CGM, after which participants were randomized to either rt-CGM or flash for 8 weeks. All participants were then given the option to continue with rt-CGM for another 8 weeks. Glycemic outcomes at 8 weeks are compared with the 16-week endpoint. Finally, 40 adults with T1D on MSIs and with IAH or a recent episode of severe hypoglycemia were included (40% female, median [IQR] age 49.5 [37.5–63.5]

years, with a diabetes duration of 30.0 [21.0–36.5] years, HbA1c 56 [48–63] mmol/mol, and Gold Score 5[4–5]), of whom 36 completed the final 16-week extension. It was shown that there was a significant reduction in percentage time in hypoglycemia (<3.0 mmol/L) in the group switching from flash to rt-CGMS (from 5.0 [3.7–8.6]% to 0.8 [0.4–1.9]%, P = 0.0001), whereas no change was observed in the rt-CGMS group continuing with the additional 8 weeks of rt-CGMS (1.3 [0.4–2.8] vs. 1.3 [0.8–2.5], P = 0.82) amd time in target range (3.9–10 mmol/L) increased in the flash group after switching to rt-CGMS (60.0 [54.5–67.8] vs. 67.4 [56.3–72.4], P = 0.02) and remained the same in the RT-CGM group that continued with RT-CGM (65.9 [54.1–74.8] vs. 64.9 [49.2–73.9], P = 0.64). It was concluded that switching from flash to RT-CGM has a significant beneficial impact on hypoglycemia outcomes and that continued use of RT-CGM maintains hypoglycemia risk benefit in this high-risk population.

Hasaga etal conducted a trial recently to compare the efficacy of real-time and intermittently scanned continuous glucose monitoring (rtCGM and isCGM, respectively) in maintaining optimal glycemic control in T1D patients with normal hypoglycemia awareness (Gold score <4). They used rtCGM (Guardian Connect Mobile) or isCGM (FreeStyle Libre) during 4 days of physical activity (exercise phase) and in the subsequent 4 weeks at home (home phase). Primary end points were time in hypoglycemia (<3.9 mmol/L [<70 mg/dL]) and time in range (3.9–10.0 mmol/L [70–180 mg/dL]). The isCGM group wore an additional masked Enlite sensor (iPro2) for 6 days to check for bias between the different sensors used by the rtCGM and isCGM systems. In total, 60 adults with T1D (mean age 38613 years; A1C 62612 mmol/mol [7.861.1%]) were randomized to rtCGM (n =30) or isCGM (n=30). It was found that percentage of time in hypoglycemia (<3.9 mmol/L [<70 mg/dL]) was lower among rtCGM versus isCGM participants in the exercise phase (6.865.5% vs. 11.468.6%,

respectively; P50.018) and during the home phase (5.362.5% vs. 7.36 4.4%, respectively; P 5 0.035) with hypoglycemia differences being most notable during the night. Also, rtCGM participants spent more time in range (3.9–10 mmol/L [70–180 mg/dL]) than isCGM participants throughout both the exercise (78.5610.2% vs. 69.7616%, respectively; P50.0149) and home (75.669.7% vs. 67.4 6 17.8%, respectively; P 5 0.0339) phases. Final conclusion was that rtCGM was superior to isCGM in reducing hypoglycemia and improving time in range in adults with T1D with normal hypoglycemia awareness, demonstrating the value of rtCGM alarms during exercise and in daily diabetes self management.

To the best of our knowledge only one study comparing rt-CGMS vs is-CGMS is there in T1D adult patients in individuals with normal hypoglycemic awareness. With multiple limtations like no cross-over and no assessment of change in HbA1c and CGMS device being continuously worn which is not practical in our scenario.

The current thesis protocol supersedes on these limitations.

HYPOTHESIS

rt-CGMS is better than is-CGMS for short term effect on glycemic control which also will be translated into longer term glycemic control as reflected by improvement in HbA1c.

We are postulating that by application of CGMS for 2 weeks glycemic patterns of individual patients will be identified and the education provided in this regard will change the insight of the individual towards his disease which will culminate in better longer term blood glucose control and already previous studies have shown that glucose readings from the most recent 14 days correlate strongly with 3 months of mean blood glucose, time in ranges, and hyperglycemia metrics (33,34).

Primary objective:

To study the effects of rtCGM vs isCGM on:

- Reduction in HbA1c (at the end of 3 months).

Secondary objectives:

- Reduction in glycemic variability.
- Reduction in hypoglycemic events in adults with Type-1 Diabetes.
- Reduction in Fructosamine (at the end of 2 weeks).
- Quality of life as assessed by QOLID (Nagpal etal) Questionnaire

MATERIALS AND METHODS

1. **Study design**: Open label crossover RCT with 3 arms
2. **Sample size**: Sample size of 17 is requires for a power of 80% to detect 0.5% change in HbA1c between both groups with an alpha of 0.05, Assuming 10% attrition in each group 20 patients will be recruited in all rt-CGMS and is-CGMS and 40 in SMBG arms.
3. **Subjects**: Patients attending Endocrinology OPD at PGIMER Chandigarh
4. **Study Period**: I5th June 2023 to 15th February 2024(last enrolment on 15th August 2023) and last follow up on 15th February 2024.
5. **Study Center**: PGIMER, Chandigarh
6. **Study Population**: Patients who fulfill inclusion and exclusion criteria will be recruited from OPD.

Inclusion criteria :

- Adolescents and adults ≥15 years with Type-1 Diabetes mellitus defined by any of the following;
    - Diabetic Ketoacidosis or ketonemia or ketonuria at diagnosis with insulin dependence for survival since diagnosis OR
    - Insulin dependence for survival since diagnosis and any one of the following autoantibody positivity: GAD-65 or IA-2
- Patients on Basal bolus regimen **(Glargine as basal and lispro/Aspart/Glulisine as bolus);**
- Duration of Diabetes > 2 years;

- Insulin dose requirement of at least 0.5U/kg
- HbA1c 8%-12%;
- Gold score<4;
- No previous experience with rt-CGMS and/or is-CGMS;
- Euthyroid status;
- If hypothyroid, then on stable dose of Levothyroxine for last 3 months with normal T4 level;
- Urine albumin creatinine ratio<300 mg/g of Creatinine;
- Those willing to give informed consent prior to enrolment.

EXCLUSION CRITERIA:

- LADA or Secondary Diabetes
- eGFR<60ml/min/1.73$\boldsymbol{m^2}$
- Celiac disease;
- Hb<12g/dl for males and <11g/dl for females;
- Hypoglycemia unawareness defined by Gold score≥4;
- HbA1c>12%;
- DKA in previous 3 months;
- Severe Non proliferative Diabetic retinopathy/Proliferative DR/Macular edema;
- Pregnancy;
- Lactation;
- Willing to become pregnant during study;
- Requiring MRI for any existing condition;
- Any chronic illness.

METHODOLOGY

Participants meeting inclusion criteria will be randomized to rt-CGMS, is-CGMS and SMBG arms. Randomization will be done using computer generated random number list. Blocks of patients with HbA1c 8%-10% and 10%-12% will be distributed equally in all 3 groups.

Sample Size: With a 1:1:2randomization ratio in 3 arms with sample size of 20:20:40 participants in each groups will be required.

Initial training of 2 weeks for all enrolled patients in each of 3 groups about the disease itself, ICR, ISF, carbohydrate counting and bolus dose adjustment based on these parameters will be done, for premeal boluses.**Only those patients will be enrolled who are using Lispro/Aspart/Glulisine for their diabetes control**. All adults enrolled in the rt-CGM group will be placed on rt-CGM Medtronic CGMS for 2 weeks and finger-prick blood glucose will also be monitored by glucometer (SMBG) 3 times on day 1 and then at least 2 times per day with proper record of time. All patients will use same glucometer for SMBG. Physical exercise of at least 30 mins aerobic activity will be required in all patients.

After a week a new Medtronic CGMS will be applied as per the manufacturer recommendation. Those randomized into is-CGM will be placed on Abott Libre Flash system for 2 weeks. A 3rd group on SMBG will also be there (doing SMBG 4 times a

day- Before breakfast, Before Lunch, and Before Dinner and post meal (after any one meal on rotational basis) and **7 point profile once a week on Sunday**).

During this 2 week intervention phase all the patients will be monitored daily telephonically along with once in a week follow-up visit.

Fructosamine assay will be repeated after 2 weeks in rt-CGMS and is-CGMS groups and glycemic control compared. Thereafter the 3 groups shall use SMBG for monitoring glycemic status as in SMBG group and HbA1c will be repeated at the end of 3 months.

CGMS metrics of the 2 weeks (TBR, TIR ,TAR etc) will be compared in both groups as per ADA recommendations and those with <70% data available will be kept on a new device.

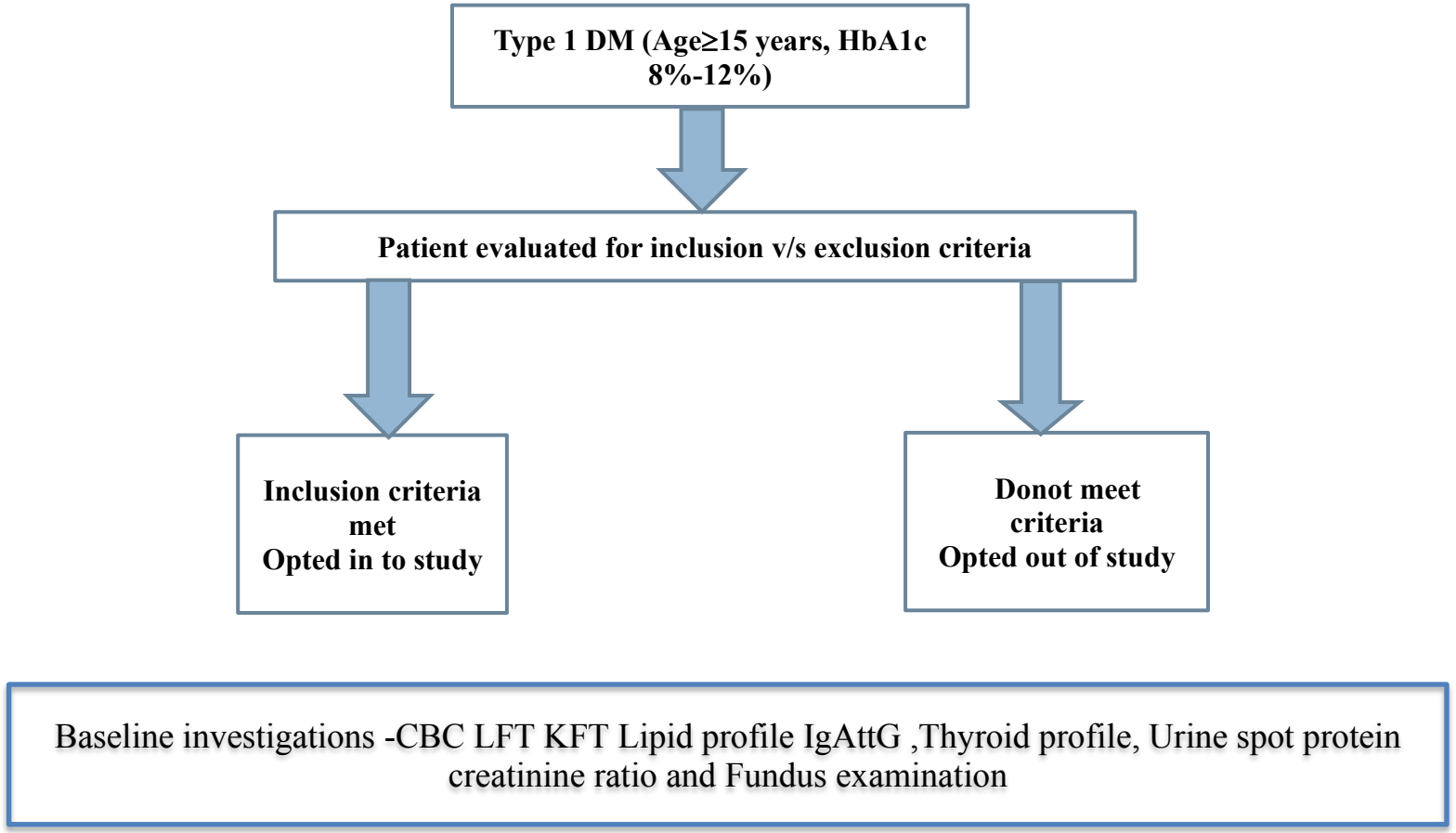
At the end of 3 months direct cross-over of rt-CGMS group to new is-CGMS group and is-CGMS group to new rt-CGMS group will be done and again fructosamine assay shall

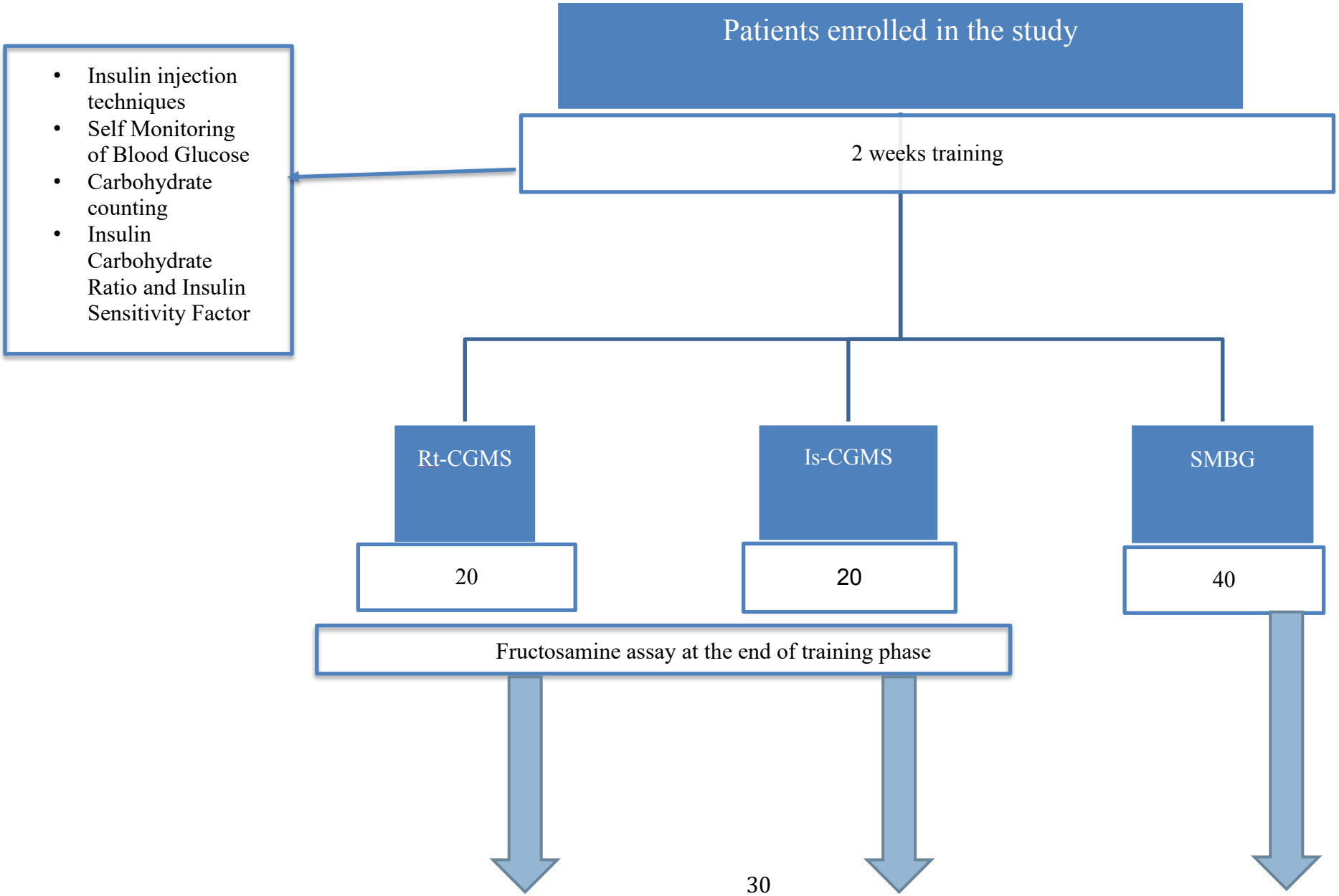
be done at the baseline and at the end of 2 weeks. Thereafter, all the 3 groups shall use same glucometer for SMBGtill the end of 6 months where HbA1c will be estimated. Hence, for each participant total 6 months of data will be recorded. Individuals will act as their own control thereby removing confounding factors in analysis

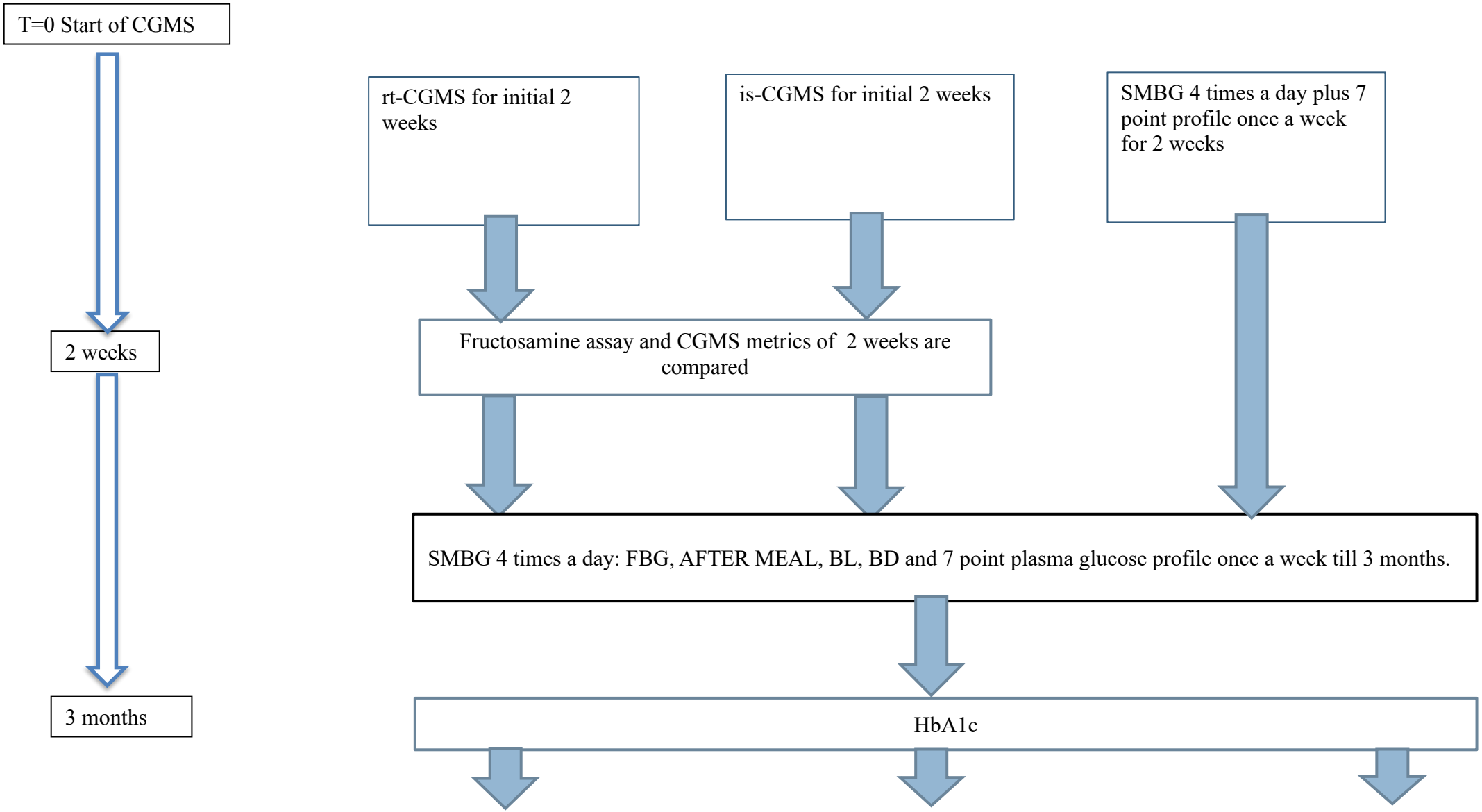
be done at the baseline and at the end of 2 weeks. Thereafter, all the 3 groups shall use same glucometer for SMBG till the end of 6 months where HbA1c will be estimated. Hence, for each participant total 6 months of data will be recorded. Individuals will act as their own control thereby removing confounding factors in analysis.

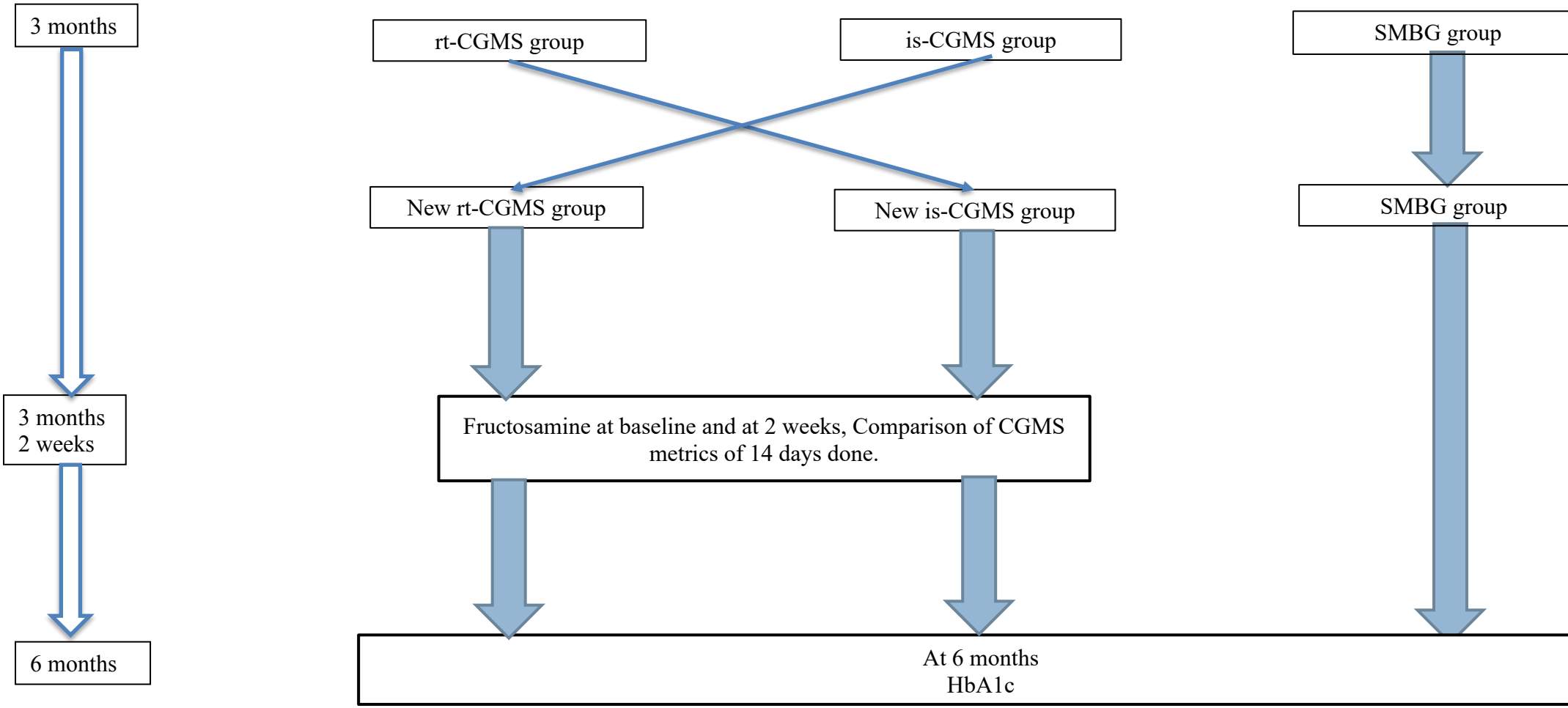
All these insulins and CGM systems are a part of routine standard care in management of Type-1 Diabetes Mellitus as endorsed by American Diabetic Association in 2022.

FLOW CHART OF STUDY PROTOCOL




Patients enrolled in the study
2 weeks training
Insulin injection techniques
Self Monitoring of Blood Glucose
Carbohydrate counting
Insulin Carbohydrate Ratio and Insulin Sensitivity Factor
Rt-CGMS
Is-CGMS
SMBG
20
20
40
Fructosamine assay at the end of training phase


T=0 Start of CGMS
2 weeks
3 months
rt-CGMS for initial 2 weeks
is-CGMS for initial 2 weeks
SMBG 4 times a day plus 7 point profile once a week for 2 weeks
Fructosamine assay and CGMS metrics of 2 weeks are compared
SMBG 4 times a day: FBG, AFTER MEAL, BL, BD and 7 point plasma glucose profile once a week till 3 months.
HbA1c


3 months
3 months
2 weeks
6 months
rt-CGMS group
is-CGMS group
SMBG group
New rt-CGMS group
New is-CGMS group
SMBG group
Fructosamine at baseline and at 2 weeks, Comparison of CGMS metrics of 14 days done.
At 6 months
HbA1c

OUTCOME VARIABLES TO BE STUDIED

- Glycemic variability as assed by CGMS
- Daily average insulin requirement per kg body weight
- Fructosamine assay after 2 weeks in rt-CGMS group and is-CGMS group and HbA1c in each of the 3 groups at end of 3 and 6 months respectively;
- Number of hypoglycemic events especially nocturnal and exercise related events;
- Any complications related to CGM;
- Quality of Life by QOLID (Nagpal etal) Questionnaire**.**

Statistical Analysis:

Statistical analysis will be performed according to the results obtained from parameters. Discrete categorical data will be represented in the form of either a number or a percentage (%), continuous data, assumed to be normally distributed, will be written as either in the form of its mean and standard deviation or in the form of its median and interquartile range, as per the requirement. The normality of quantitative data will be checked by measures of Kolmogorov-Smirnov tests of normality. ANOVA or Mann Whitney U test will be applied to compare 3 groups at a time depending upon the normality of the data. Proportions will be compared using Chi square or Fisher's exact test, depending on their applicability for 3 groups. All the statistical tests will be two-sided and will be performed at a significance level of $P<0.05$. Analysis will be conducted using IBM SPSS STATISTICS (version 22.0)

ETHICAL JUSTIFICATION

Following ethical considerations will be adhered to during the study:

1. Patients will be enrolled in the study after fully informed written consent has been taken. The patient will have right to quit the study at any point in time during the study and no compulsion will be exerted on them.

2. Patient will be informed about the aim and method of the study, investigations that will be conducted on him/her, possible adverse effects associated with the treatment modality under study even after he/she has signed the consent and he/she will be excluded from the study.

3. The patient, whether or not enrolled in the study will receive treatment as per the standard protocol followed in the Department of Endocrinology PGIMER, Chandigarh.

4. The planned study involves blood collection (10 ml) by venipuncture from T2D patients. The blood sample will be used for biochemical tests, haematological tests and Hormonal analysis.

5. Detailed education regarding CGM, methods of insertion, use and linking to smartphone wherever available will be provided.

6. Signs and symptoms of hypoglycemia will be thoroughly explained and measures to correct it shall be taught to the patients.

7. Confidentiality of data collected from contribution source or individual will be maintained.

8. The study will be conducted following the principles of Declaration of Helsinki and Good clinical Practice laid down by Indian Council of Medical Research.

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QOLID QUESTIONNAIRE

Role Limitation Due to Physical Health

1. How often do you miss your work because of your diabetes ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

2. A person with diabetes has the requirement of adhering to a schedule for eating and taking regular medication. How often does this affect your work ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

3. How often does diabetes affect your efficiency at Work ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

4. How often do you find diabetes limiting your social life ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

5. To what extent do you avoid traveling (business tour, holiday, general outings) because of your diabetes ?

A lot	Highly	Little	Very little	Not at all
1	2	3	4	5

6. Compared to others of your age are your social activities (visiting friends/partying) limited because of your diabetes?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

Physical Endurance

1. How often in last three months has your overall health problems limited the kind of vigorous activities you can do like lifting heavy bags/objects, running, skipping, jumping.

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

2. How often in last three months has your overall health problems limited the kind of moderate activities you can do like moving a table, carrying groceries or utensils.

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

3. How often in last three months has your overall health problems limited you from walking uphill or climbing 1-2 floors.

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

4. How often in last three months has your overall health problems limited you from walking 1-2 km at a stretch.

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

5. How often in last three months has your overall health problems limited from bending, squatting, or turning.

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

6. How often in last three months has your overall health problems limited you from eating, dressing, bathing, or using the toilet.

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

General Health

1. In general would you say your health.

Poor	Fair	Good	Very good	Excellent
1	2	3	4	5

2. How well are you able to concentrate in everything like working, driving, reading etc. ?

Not at all	A little	Moderate	Very Much	An extreme Amount
1	2	3	4	5

3. How many times in the past three months have you had fatigue/felt very tired ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

Treatment Satisfaction

The following set of questions would enable us to know how satisfied are you with your treatment for diabetes. Please tick any one option.

1. How satisfied are you with your current diabetes treatment ?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

2. How satisfied are you with amount of time it takes to manage your diabetes ?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

3. How satisfied are you with the amount of time you spend getting regular checkups (once in 3 months) ?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

2. A person with diabetes needs to exercise for 35-45 min, 4 times a week. Keeping this in mind how satisfied are you with the time you spend exercising ?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

Financial Worries

The following set of questions will help us know how your diabetes has affected your or your family's finances. Please tick any one option.

1. What do you think about the cost involved in your management of diabetes ?

Very expensive	Little expensive	Reasonable	Not at all expensive
1	2	3	4

2. To what extent has your priority of expenditure shifted towards diabetes management ?

A lot	Highly	Little	Very Little	Not at all
1	2	3	4	5

3. To what extent has your family budget got affected by the expenses related to the management of diabetes ?

A lot	Highly	Little	Very Little	Not at all
1	2	3	4	5

Symptom Botherness

1. How many times in the past three months have you had thirst/dry mouth ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

2. How many times in the past three months have you felt excessive hunger ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

3. How many times in the past three months have you had frequent urination related to diabetes management ?

Always	Frequency	Often	Sometimes	Never
1	2	3	4	5

4. To what extent has your diabetes limited your expenditure on other aspects of life (Moving, outings, parties etc.)?

A lot	Highly	Little	Very Little	Not at all
1	2	3	4	5

Emotional/Mental Health

1. How satisfied are you with yourself ?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

2. How satisfied are you with your personal relationships (family, friends, relatives and known tos)

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

3. How satisfied are you with the emotional support you get from your friends and family ?

Very dissatisfied	Moderately dissatisfied	Neither satisfied nor dissatisfied	Moderately satisfied	Very satisfied
1	2	3	4	5

4. How often are you discouraged by your health problems ?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

5. All people want to fulfill certain roles and lead their lives in a purposeful manner. To what extent do you feel that you have been able to lead your life in the same way ?

Not at all	A little	Moderate	Very much	An extreme amount
1	2	3	4	5

Diet Satisfaction

Diabetes demands a little modification in diet, thus the following set of questions would help us know how much satisfied you are with modifications in your diet ?
(For participants who have been advised some dietary modification/counseling)

1. How often do you feel because of your diabetes a restriction in choosing your food when eating out ?

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

2. As you have diabetes, how much choice od you feel you have in eating your meals or snacks away from home e.g. if you go in a party and there is a buffet where there are also a lot of fried snacks and desserts would you be able to make enough choice ?

No choice	Very little	Little	Enough	A lot
1	2	3	4	5

3. How often do you eat the food items that you shouldn't, in order to hide the fact that you are having diabetes.

Always	Frequently	Often	Sometimes	Never
1	2	3	4	5

Informed Consent Form (ICF)

Study Title:

"Comparison of real-time CGMS with intermittently-scanned CGMS in adolescents and adults with Type 1 Diabetes Mellitus: An Open Label Randomised Control Cross Over Study".

Study Number (if any):

Subject's Initials: _____

Subject's Name:_____

Date of Birth / Age: _____

Participant's initial

1. I confirm that I have read and understood the information sheet dated _ _ _ _ for the above study and have had the opportunity to ask questions.

2. I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published.
4. I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s)

5. I agree to take part in the above study

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative:_____

Date: _____/_____/_____

Signatory's Name: _____

Signature of the Investigator: _____

Date:_____/_____/_____

Study Investigator's Name: _____

सूचित सहमति फॉर्म (आईसीएफ)

अध्ययन का शीर्षक: "टाइप 1 डायबिटीज मेलिटस वाले किशोरों और वयस्कों में रुक-रुक कर स्कैन किए गए सीजीएमएस के साथ रीयल-टाइम सीजीएमएस की तुलना: एक ओपन लेबल रैंडमाइज्ड कंट्रोल क्रॉस ओवर स्टडी"।
अध्ययन संख्या (यदि कोई हो):
विषय के आद्याक्षर: _____
विषय का नाम:_____
जन्म तिथि / आयु: _____

प्रतिभागी का आद्याक्षर

1. मैं पुष्टि करता हूं कि मैंने उपरोक्त अध्ययन के लिए सूचना पत्र दिनांक__ को पढ़ और समझ लिया है और मुझे प्रश्न पूछने का अवसर मिला है।

2. मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और यह कि मैं किसी भी समय, बिना कोई कारण बताए, अपनी चिकित्सा देखभाल या कानूनी अधिकारों को प्रभावित किए बिना वापस लेने के लिए स्वतंत्र हूं।

3. मैं समझता हूं कि नैदानिक परीक्षण के प्रायोजक, प्रायोजक की ओर से काम करने वाले अन्य लोग, आचार समिति और नियामक प्राधिकरण वर्तमान अध्ययन और किसी भी अन्य शोध के संबंध में मेरे स्वास्थ्य रिकॉर्ड को देखने के लिए मेरी अनुमति की आवश्यकता नहीं होगी इसके संबंध में, भले ही मैं मुकदमे से हट जाऊं। मैं इस पहुंच से सहमत हूं।

हालांकि, मैं समझता हूं कि मेरी पहचान किसी में भी जाहिर नहीं की जाएगी– तृतीय पक्षों को जारी की गई जानकारी या प्रकाशित।

4. मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणाम के उपयोग को प्रतिबंधित नहीं करने के लिए सहमत हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्य के लिए हो।

5. मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं

विषय/कानूनी रूप से स्वीकार्य प्रतिनिधि के हस्ताक्षर (या अंगूठे का निशान):_____
तारीख: ____/____/_____
हस्ताक्षरकर्ता का नाम: _____
अन्वेषक के हस्ताक्षर: _____
तारीख:____/____/_____
अध्ययन अन्वेषक का नाम: _____

ਸੂਚਿਤ ਸਹਿਮਤੀ ਫਾਰਮ •ICF)

ਅਧਿਐਨ ਦਾ ਸਿਰਲੇਖû“ਟਾਈਪ À ਡਾਇਬਟੀਜ਼ ਮਲੇਟਸ ਵਾਲੇ ਕਿਸ਼ੋਰਾਂ ਅਤੇ ਬਾਲਗਾਂ ਵਿੱਚ ਰੁਕ≈ਚੁਕ ਕੇ ਸਕੈਨ ਕੀਤੇ CGMS ਨਾਲ ਅਸਲ≈ਸਮੇਂ ਦੇ CGMS ਦੀ ਤੁਲਨਾûਇੱਕ ਓਪਨ ਲੇਬਲ ਰੈਂਡਮਾਈਜ਼ਡ ਕੰਟਰੋਲ ਕਰਾਸ ਓਵਰ ਸਟੱਡੀ”।

ਅਧਿਐਨ ਨੰਬਰ •ਜੇ ਕੋਈ ਹੈ¶û

ਵਿਸ਼ੇ ਦੇ ਸ਼ੁਰੂਆਤੀ ਅੱਖਰû_____

ਵਿਸ਼ੇ ਦਾ ਨਾਮû_____

ਜਨਮ ਮਿਤੀ ¨ ਉਮਰû_____

ਭਾਗੀਦਾਰ ਦਾ ਸ਼ੁਰੂਆਤੀ

Àü ਮੈਂ ਪੁਸ਼ਟੀ ਕਰਦਾ¨ਕਰਦੀ ਹਾਂ ਕਿ ਮੈਂ ਉਪਰੋਕਤ ਅਧਿਐਨ ਲਈ ਮਿਤੀ _ _ _ _ ਦੀ ਜਾਣਕਾਰੀ ਸ਼ੀਟ ਨੂੰ ਪੜ੍ਹ ਅਤੇ ਸਮਝ ਲਿਆ ਹੈ ਅਤੇ ਮੈਨੂੰ ਸਵਾਲ ਪੁੱਛਣ ਦਾ ਮੌਕਾ ਮਿਲਿਆ ਹੈ।

Áü ਮੈਂ ਸਮਝਦਾ¨ਸਮਝਦੀ ਹਾਂ ਕਿ ਅਧਿਐਨ ਵਿੱਚ ਮੇਰੀ ਭਾਗੀਦਾਰੀ ਸਵੈਇੱਛਤ ਹੈ ਅਤੇ ਇਹ ਕਿ ਮੈਂ ਕਿਸੇ ਵੀ ਸਮੇਂ, ਬਿਨਾਂ ਕੋਈ ਕਾਰਨ ਦੱਸੇ, ਮੇਰੀ ਡਾਕਟਰੀ ਦੇਖਭਾਲ ਜਾਂ ਕਾਨੂੰਨੀ ਅਧਿਕਾਰਾਂ ਨੂੰ ਪ੍ਰਭਾਵਿਤ ਕੀਤੇ ਬਿਨਾਂ ਵਾਪਸ ਲੈਣ ਲਈ ਸੁਤੰਤਰ ਹਾਂ।

Âü ਮੈਂ ਸਮਝਦਾ¨ਸਮਝਦੀ ਹਾਂ ਕਿ ਕਲੀਨਿਕਲ ਟ੍ਰਾਇਲ ਦੇ ਸਪਾਂਸਰ, ਸਪਾਂਸਰ ਦੀ ਤਰਫੋਂ ਕੰਮ ਕਰ ਰਹੇ ਹੋਰ ਲੋਕ, ਐਥਿਕਸ ਕਮੇਟੀ ਅਤੇ ਰੈਗੂਲੇਟਰੀ ਅਥਾਰਟੀਆਂ ਮੌਜੂਦਾ ਅਧਿਐਨ ਅਤੇ ਹੋਰ ਕਿਸੇ ਵੀ ਖੋਜ ਦੇ ਸਬੰਧ ਵਿੱਚ ਮੇਰੇ ਸਿਹਤ ਰਿਕਾਰਡਾਂ ਨੂੰ ਦੇਖਣ ਲਈ ਮੇਰੀ ਇਜਾਜ਼ਤ ਦੀ ਲੋੜ ਨਹੀਂ ਹੋਵੇਗੀ ਜੋ ਇਸ ਵਿੱਚ ਕੀਤੀ ਜਾ ਸਕਦੀ ਹੈ ਇਸ ਨਾਲ ਸਬੰਧਤ, ਭਾਵੇਂ ਮੈਂ ਮੁਕੱਦਮੇ ਤੋਂ ਪਿੱਛੇ ਹਟ ਜਾਂਦਾ ਹਾਂ। ਮੈਂ ਇਸ ਪਹੁੰਚ ਲਈ ਸਹਿਮਤ ਹਾਂ।

ਹਾਲਾਂਕਿ, ਮੈਂ ਸਮਝਦਾ ਹਾਂ ਕਿ ਮੇਰੀ ਪਛਾਣ ਕਿਸੇ ਵੀ ਰੂਪ ਵਿੱਚ ਪ੍ਰਗਟ ਨਹੀਂ ਕੀਤੀ ਜਾਵੇਗੀ ਤੀਜੀ ਧਿਰ ਨੂੰ ਜਾਰੀ ਕੀਤੀ ਜਾਂ ਪ੍ਰਕਾਸ਼ਿਤ ਕੀਤੀ ਗਈ ਜਾਣਕਾਰੀ।

o ਮੈਂ ਇਸ ਅਧਿਐਨ ਤੋਂ ਪੈਦਾ ਹੋਣ ਵਾਲੇ ਕਿਸੇ ਵੀ ਡੇਟਾ ਜਾਂ ਨਤੀਜਿਆਂ ਦੀ ਵਰਤੋਂ 'ਤੇ ਪਾਬੰਦੀ ਨਾ ਲਗਾਉਣ ਲਈ ਸਹਿਮਤ ਹਾਂ ਬਸ਼ਰਤੇ ਕਿ ਅਜਿਹੀ ਵਰਤੋਂ ਕੇਵਲ ਵਿਗਿਆਨਕ ਉਦੇਸ਼ਾਂ ਲਈ ਹੋਵੇ।

o ਮੈਂ ਉਪਰੋਕਤ ਅਧਿਐਨ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਸਹਿਮਤ ਹਾਂ

ਵਿਸ਼ੇ ਕਾਨੂੰਨੀ ਤੌਰ 'ਤੇ ਸਵੀਕਾਰਯੋਗ ਪ੍ਰਤੀਨਿਧੀ ਦੇ ਦਸਤਖਤ ਜਾਂ ਅੰਗੂਠੇ ਦਾ ਨਿਸ਼ਾਨ

_____

ਤਾਰੀਖ਼____/____/_____

ਹਸਤਾਖਰ ਕਰਨ ਵਾਲੇ ਦਾ ਨਾਮ_____

ਜਾਂਚਕਰਤਾ ਦੇ ਦਸਤਖਤ_____

ਤਾਰੀਖ਼____/____/_____

ਅਧਿਐਨ ਜਾਂਚਕਰਤਾ ਦਾ ਨਾਮ_____

PATIENT INFORMATION SHEET

PRINCIPAL INVESTIGATOR: Dr. Sanjay Kumar Bhadada

Phone Number: +919876602448

Study title: COMPARISON OF REAL-TIME CGMS WITH INTERMITTENTLY

SCANNED CGMS IN ADOLESCENTS AND ADULTS WITH TYPE 1 DIABETES MELLITUS: AN OPEN LABEL RANDOMISED CONTROL CROSS OVER STUDY

Invitation: You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read following information carefully and discuss with your friends, relatives or your family doctor if you wish to. Ask us if there is anything that is not clear or you would like to know more about the study.

1. What is the purpose of the study?

   To compare the efficacy of rt-CGM vs is-CGM on improvement in glycemic profile at end of 3 months and 6 months in T1DM patients.

2. What is the expected duration of the study?

   Expected duration for the study is 6 months

3. Why have I been chosen?

   You have been chosen as a patient suffering from Type 1 Diabetes Mellitus.

4. What are the benefits from this research?

   After participation in this study , you would be able to do carbohydrate counting and adjust insulin doses according to your meal content and pre-meal blood glucose values which will improve your meal flexibility without any compromise with your blood glucose control. Moreover, there would be 3 groups in this study and if you are randomized into one of the two CGMS groups, CGMS will be provided to you and by this technology your meal patterns and blood glucose fluctuations will be analysed and your insulin dosages will be modified accordingly. If you are randomized to SMBG group, you will be under close monitoring and supervision of a specialist and your insulin dosages would be modified as per the

standard of care. Irrespective of randomization in any of the groups, your blood glucose control is expected to improve during this study.

Through this research we are hypothesizing that only 2 week use of CGMS is enough to uncover your glycemic patterns, which is cost effective and the behavioural changes and therapeutic changes made in your treatment regime by the analysis of 2 week CGMS report will have an impact on your blood glucose control as reflected in your HbA1c at 3 months. Most of the studies have used continuous application of CGMS which is not practical in our country.

5. Do I have to take part?

It is up to you to decide whether or not to take part? If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason. Even if you decide, not to take part in this study, this will not affect the standard of care you receive.

6. What will happen to me if I take part?

You will have to sign consent. You will be physically examined. You have to give blood samples periodically and you can be kept in either of rt-CGMS or is-CGMS groups. Standard treatment of T1D will be provided irrespective of randomization in any group.

7. What are the alternatives available to you?

This is not a drug trial and we are only monitoring your blood glucose levels by CGMS, in case you don't want to participate in this trial you can use Self monitoring of blood glucose by multiple finger pricks as is the standard of care for management of type 1 diabetes.

8. What are the possible risks of taking part in study?

There is almost no risk involved in this study because only blood samples and CGMS and SMBG for glucose profile will be done which is usual standard of care in T1D. You shall be under strict monitoring throughout our study

9. What will be the treatment schedule in this study?

The study will include 80 participants and you will be randomized to rt-CGMS, is-CGMS or SMBG arm using computer generated random number list. Initial training of 2 weeks for all enrolled patients in each of 3 groups about the disease itself, ICR, ISF, carbohydrate counting and bolus dose adjustment based on these parameters will be done, for premeal boluses. If you are randomized into the rt-CGM group will be placed on rt-CGM Medtronic CGMS for 2 weeks ;if in is-CGM group, u will be provided Abott Libre Flash system for 2 weeks and if in SMBG group, u will monitor blood glucose by multiple finger pricks at least 4 times a day- Before breakfast, Before Lunch, and Before Dinner and post meal (after any one meal on rotational basis) on weekdays and 7 point profile once a week on Sunday. After 3 months, you will be switched to other CGMS group if u were in any of the CGMS groups, however, if you were in SMBG group, you will continue to be in that group till the end of this study.

10. How much blood will be taken for investigations and at what time points?

    2ml of blood will be taken after the end of training phase (2 weeks), then after the end of CGMS device application (4 weeks) and at three months and three and a half month and finally at 6 months 2 weeks (**total 8 ml** blood will be taken for each patient over a period of 6 months)"(**total four times** in CGMS group). In SMBG group 2ml of blood will be taken after the end of training phase (2 weeks), at 3 months and 2 weeks and finally at 6 months 2 weeks (**total 6 ml** of blood over a period of 6 months for each patient) ;**in total 3 times** during the study.

11. Will my talking part of this study kept confidential?

All information collected about you during the course study will be kept confidential.

12. What compensation and or treatments are available in case of trial related injury?

    The intervention we are doing here is application of Continuous Glucose Monitoring System for 14 days which is the standard of care for Type-1 Diabetes Mellitus as advocated by different guidelines (ref ADA 2022), all patients will receive the standard of care treatment (Insulin for type 1 diabetes) and no novel treatment is

being introduced. Henceforth, it is not expected that any patient will develop any adverse event because of the particular intervention in the study as we are monitoring their glucose level only. However if any patient develops hypoglycemia including severe hypoglycemia (which may otherwise happen in any individual patient of type 1 diabetes on insulin therapy) will be managed as per routine clinical care including hospital admission if needed.

13. Are the participants paid to take part in this study?

    The participants will be reimbursed for their extra study related visits as per the norms. Apart from this no extra money will be provided to them. There will be no additional costs to be borne by the participants for participation in this study.

14. What will be done with the results of study?

    Results of the research may be published. We assure you that you will not be identified by name in any report/publication.

15. Who is organizing the research?

    Department of Endocrinology, PGIMER, Chandigarh are organizing this research

16. Who has reviewed this study?

    Ethics committee of the institution will review the study.

17. Whom can I contact if for any query or grievance?

    You can contact the following:

1. Principal Investigator- Dr. Sanjay Kumar Bhadada, Head of Department, Department of Endocrinology Room number 1, Ground floor, Nehru Hospital Extension, PGIMER, Chandigarh-160012, Phone Number: +919876602448
2. Institute Ethics Committee, PGIMER - 6th floor PN Chuttani Block, Chandigarh- 160012, Phone number: 0172-2755266.

रोगी सूचना पत्र

मुख्य अन्वेषक: डॉ. संजय कुमार भड़ाडा

फोन नंबर: +919876602448

अध्ययन शीर्षक: ग्लाइसेमिक नियंत्रण में रीयल-टाइम सीजीएमएस बनाम आंतरायिक रूप से स्कैन किए गए सीजीएमएस और टाइप 1 मधुमेह मेलिटस रोगियों के समूह में परिवर्तनशीलता: क्लिनिकल नियंत्रण अध्ययन पर एक खुला लेबल अध्ययन

आमंत्रण: आपको एक शोध अध्ययन में भाग लेने के लिए आमंत्रित किया जा रहा है। निर्णय लेने से पहले आपके लिए यह समझना महत्वपूर्ण है कि शोध क्यों किया जा रहा है और इसमें क्या शामिल होगा। कृपया निम्नलिखित जानकारी को ध्यान से पढ़ने के लिए समय निकालें और यदि आप चाहें तो अपने दोस्तों, रिश्तेदारों या अपने परिवार के डॉक्टर से चर्चा करें। हमसे पूछें कि क्या कुछ ऐसा है जो स्पष्ट नहीं है या आप अध्ययन के बारे में अधिक जानना चाहते हैं।

1. अध्ययन का उद्देश्य क्या है?

T1D रोगियों में 3 महीने के अंत में ग्लाइसेमिक प्रोफाइल में सुधार पर RT-CGM बनाम is-CGM की प्रभावकारिता की तुलना करना

2. अध्ययन की अपेक्षित अवधि क्या है?

अध्ययन के लिए अपेक्षित अवधि 6 महीने है

3. मुझे क्यों चुना गया है: आपको टाइप 1 डायबिटीज मेलिटस से पीड़ित रोगी के रूप में चुना गया है।

4. इस शोध से क्या लाभ हैं?

इस अध्ययन में भाग लेने के बाद, आप अपने भोजन की मात्रा और भोजन से पहले के रक्त ग्लूकोज मूल्यों के अनुसार कार्बोहाइड्रेट की गिनती और इंसुलिन खुराक को समायोजित करने में सक्षम होंगे, जो आपके रक्त ग्लूकोज नियंत्रण के साथ किसी भी तरह का समझौता किए बिना आपके भोजन के लचीलेपन में सुधार करेगा। इसके अलावा, इस अध्ययन में 3 समूह होंगे और यदि आपको दो सीजीएमएस समूहों में से एक में यादृच्छिक किया जाता है, तो आपको सीजीएमएस प्रदान किया जाएगा और इस तकनीक द्वारा आपके भोजन के पैटर्न और रक्त शर्करा के उतार-चढ़ाव का विश्लेषण किया जाएगा और आपके इंसुलिन की खुराक को संशोधित किया जाएगा। इसलिए। यदि आपको एसएमबीजी समूह में यादृच्छिक रूप से शामिल किया गया है, तो आप एक विशेषज्ञ की करीबी निगरानी और पर्यवेक्षण के अधीन होंगे और आपकी इंसुलिन खुराक को देखभाल के मानक के अनुसार संशोधित किया जाएगा। किसी भी समूह में यादृच्छिकीकरण के बावजूद, इस अध्ययन के दौरान आपके रक्त शर्करा नियंत्रण में सुधार होने की उम्मीद है।

इस शोध के माध्यम से हम परिकल्पना कर रहे हैं कि सीजीएमएस का केवल 2 सप्ताह का उपयोग आपके ग्लाइसेमिक पैटर्न को उजागर करने के लिए पर्याप्त है, जो कि लागत प्रभावी है और 2 सप्ताह की सीजीएमएस रिपोर्ट के विश्लेषण से आपके उपचार व्यवस्था में किए गए व्यवहारिक परिवर्तन और उपचारात्मक परिवर्तन पर प्रभाव पड़ेगा। 3 महीने में आपके रक्त शर्करा नियंत्रण को आपके एचबीए1सी में दर्शाया गया है। अधिकांश अध्ययनों में सीजीएमएस के निरंतर अनुप्रयोग का उपयोग किया गया है जो हमारे देश में व्यावहारिक नहीं है।

5. क्या मुझे भाग लेना है?

यह आपको तय करना है कि भाग लेना है या नहीं? यदि आप भाग लेने का निर्णय लेते हैं तो आपको यह सूचना पत्र रखने के लिए दिया जाएगा और सहमति फॉर्म पर

हस्ताक्षर करने के लिए कहा जाएगा। यदि आप भाग लेने का निर्णय लेते हैं, तब भी आप बिना कोई कारण बताए किसी भी समय अपना नाम वापस लेने के लिए स्वतंत्र हैं। यदि आप इस अध्ययन में भाग न लेने का निर्णय भी लेते हैं, तो इससे आपको प्राप्त होने वाली देखभाल के स्तर पर कोई प्रभाव नहीं पड़ेगा।

6. यदि मैं भाग लेता हूँ तो मेरा क्या होगा?

आपको सहमति पर हस्ताक्षर करना होगा। आपकी शारीरिक जांच की जाएगी। आपको समय-समय पर रक्त के नमूने देने होते हैं और आपको आरटी-सीजीएमएस या आईएस-सीजीएमएस समूहों में से किसी एक में रखा जा सकता है। किसी भी समूह में रैंडमाइजेशन के बावजूद टी1डी का मानक उपचार प्रदान किया जाएगा।

7. आपके पास क्या विकल्प उपलब्ध हैं?

यह कोई दवा परीक्षण नहीं है और हम केवल सीजीएमएस द्वारा आपके रक्त शर्करा के स्तर की निगरानी कर रहे हैं, यदि आप इस परीक्षण में भाग नहीं लेना चाहते हैं तो आप कई अंगुलियों की चुभन से रक्त ग्लूकोज की स्व निगरानी का उपयोग कर सकते हैं जैसा कि प्रबंधन के लिए देखभाल का मानक है टाइप 1 मधुमेह का।

8. अध्ययन में भाग लेने के संभावित जोखिम क्या हैं?

इस अध्ययन में लगभग कोई जोखिम शामिल नहीं है क्योंकि ग्लूकोज प्रोफाइल के लिए केवल रक्त के नमूने और सीजीएमएस और एसएमबीजी किए जाएंगे जो कि टी1डी में देखभाल का सामान्य मानक है। हमारे अध्ययन के दौरान आप कड़ी निगरानी में रहेंगे

9. इस अध्ययन में उपचार कार्यक्रम क्या होगा?

अध्ययन में 80 प्रतिभागियों को शामिल किया जाएगा और आपको कंप्यूटर जनित यादृच्छिक संख्या सूची का उपयोग करके rt-CGMS, is-CGMS या SMBG शाखा में यादृच्छिक किया जाएगा। बीमारी के बारे में 3 समूहों में से प्रत्येक में सभी नामांकित रोगियों के लिए 2 सप्ताह का प्रारंभिक प्रशिक्षण, इन मापदंडों के आधार पर आईसीआर, आईएसएफ, कार्बोहाइड्रेट की गिनती और बोलस खुराक समायोजन, भोजन से पहले के बोलस के लिए किया जाएगा। यदि आपको आरटी-सीजीएम समूह में रैंडमाइज किया जाता है तो आपको आरटी-सीजीएम मेडट्रॉनिक

सीजीएमएस पर 2 सप्ताह के लिए रखा जाएगा; दिन में कम से कम 4 बार कई अंगुलियों से ब्लड ग्लूकोज- नाश्ते से पहले, दोपहर के भोजन से पहले, और रात के खाने से पहले और भोजन के बाद (रोटेशनल आधार पर किसी एक भोजन के बाद) सप्ताह के दिनों में और रविवार को सप्ताह में एक बार 7 बिंदु प्रोफ़ाइल। 3 महीने के बाद, यदि आप किसी सीजीएमएस समूह में थे, तो आपको अन्य सीजीएमएस समूह में बदल दिया जाएगा, हालांकि, यदि आप एसएमबीजी समूह में थे, तो आप इस अध्ययन के अंत तक उस समूह में बने रहेंगे।

10. जांच के लिए कितना और किस समय पर ब्लड लिया जाएगा?
प्रशिक्षण चरण (2 सप्ताह) के अंत के बाद 2 एमएल रक्त लिया जाएगा, फिर सीजीएमएस डिवाइस एप्लिकेशन के अंत के बाद (4 सप्ताह) और तीन महीने और साढ़े तीन महीने और अंत में 6 महीने 2 सप्ताह (कुल 8 एमएल) 6 महीने की अवधि में प्रत्येक रोगी के लिए रक्त लिया जाएगा)" (सीजीएमएस समूह में कुल चार बार)। एसएमबीजी समूह में 2 एमएल रक्त प्रशिक्षण चरण (2 सप्ताह) के अंत के बाद, 3 महीने और 2 सप्ताह और अंत में 6 महीने 2 सप्ताह (प्रत्येक रोगी के लिए 6 महीने की अवधि में कुल 6 एमएल रक्त) लिया जाएगा; अध्ययन के दौरान कुल 3 बार।

11. क्या इस अध्ययन के मेरे बोलने वाले हिस्से को गोपनीय रखा जाएगा?
पाठ्यक्रम अध्ययन के दौरान आपके बारे में एकत्र की गई सभी जानकारी गोपनीय रखी जाएगी।

12. परीक्षण संबंधी चोट के मामले में क्या मुआवजा और/या उपचार उपलब्ध हैं?
हम यहां जो हस्तक्षेप कर रहे हैं, वह 14 दिनों के लिए निरंतर ग्लूकोज मॉनिटरिंग सिस्टम का अनुप्रयोग है जो कि टाइप -1 डायबिटीज मेलिटस की देखभाल का मानक है, जैसा कि विभिन्न दिशानिर्देशों (रेफरी एडीए 2022) द्वारा समर्थित है, सभी रोगियों को मानक देखभाल उपचार (इंसुलिन) प्राप्त होगा। टाइप 1 मधुमेह के लिए) और कोई नया उपचार पेश नहीं किया जा रहा है। अब से, यह उम्मीद नहीं की जाती है कि अध्ययन में विशेष हस्तक्षेप के कारण कोई भी रोगी किसी प्रतिकूल घटना का विकास करेगा क्योंकि हम केवल उनके ग्लूकोज स्तर की निगरानी कर

रहे हैं। हालांकि, यदि किसी मरीज में गंभीर हाइपोग्लाइसीमिया सहित हाइपोग्लाइसीमिया विकसित हो जाता है (जो इंसुलिन थेरेपी पर टाइप 1 मधुमेह के किसी भी व्यक्तिगत रोगी में अन्यथा हो सकता है) को अस्पताल में प्रवेश सहित नियमित नैदानिक देखभाल के अनुसार प्रबंधित किया जाएगा।

13. क्या प्रतिभागियों को इस अध्ययन में भाग लेने के लिए भुगतान किया जाता है?
प्रतिभागियों को मानदंडों के अनुसार उनकी अतिरिक्त अध्ययन संबंधी यात्राओं के लिए प्रतिपूर्ति की जाएगी। इसके अलावा उन्हें कोई अतिरिक्त पैसा नहीं दिया जाएगा। इस अध्ययन में भाग लेने के लिए प्रतिभागियों द्वारा कोई अतिरिक्त लागत वहन नहीं की जाएगी।

14. अध्ययन के परिणामों का क्या किया जाएगा?
शोध के परिणाम प्रकाशित किए जा सकते हैं। हम आपको विश्वास दिलाते हैं कि किसी भी रिपोर्ट/प्रकाशन में आपके नाम से आपकी पहचान नहीं होगी।

15. शोध का आयोजन कौन कर रहा है?
एंडोक्राइनोलॉजी विभाग, पीजीआईएमईआर, चंडीगढ़ इस शोध का आयोजन कर रहा है

16. इस अध्ययन की समीक्षा किसने की है?
संस्था की एथिक्स कमेटी अध्ययन की समीक्षा करेगी।

17. किसी प्रश्न या शिकायत के लिए मैं किससे संपर्क कर सकता हूं?
आप निम्नलिखित से संपर्क कर सकते हैं:
1. प्रधान अन्वेषक- डॉ. संजय कुमार भदादा, विभागाध्यक्ष, एंडोक्राइनोलॉजी विभाग, कमरा नंबर 1, ग्राउंड फ्लोर, नेहरू हॉस्पिटल एक्सटेंशन, पीजीआईएमईआर, चंडीगढ़-160012, फोन नंबर: +919876602448

2. संस्थान आचार समिति, पीजीआईएमईआर - 6वीं मंजिल पीएन चुट्टानी ब्लॉक, चंडीगढ़- 160012, फोन नंबर: 0172-2755266।

ਮਰੀਜ਼ ਜਾਣਕਾਰੀ ਸ਼ੀਟ

ਮੁੱਖ ਜਾਂਚਕਰਤਾ: ਸੰਜੇ ਕੁਮਾਰ ਭੱਦਾ, ਡਾ

ਫੋਨ ਨੰਬਰ: +919876602448

ਅਧਿਐਨ ਸਿਰਲੇਖ: ਕਿਸਮ 1 ਡਾਇਆਬਿਟੀਜ਼ ਮੈਲੀਟਸ ਦੇ ਮਰੀਜ਼ਾਂ ਦੇ ਇੱਕ ਸਮੂਹ ਵਿੱਚ ਗਲਾਈਸੀਮਿਕ ਕੰਟਰੋਲ ਅਤੇ ਪਰਿਵਰਤਨਸ਼ੀਲਤਾ ਵਿੱਚ ਰੁਕ-ਰੁਕ ਕੇ ਸਕੈਨ ਕੀਤੇ CGMS: ਇੱਕ ਖੁੱਲ੍ਹੇ ਲੇਬਲ ਵਾਲਾ ਬੇਤਰਤੀਬ ਕੀਤਾ ਸੱਦਾ: ਤੁਹਾਨੂੰ ਇੱਕ ਖੋਜ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਲਈ ਸੱਦਾ ਦਿੱਤਾ ਜਾ ਰਿਹਾ ਹੈ। ਇਸਤੋਂ ਪਹਿਲਾਂ ਕਿ ਤੁਸੀਂ ਫੈਸਲਾ ਕਰੋ, ਤੁਹਾਡੇ ਵਾਸਤੇ ਇਹ ਸਮਝਣਾ ਮਹੱਤਵਪੂਰਨ ਹੈ ਕਿ ਖੋਜ ਨੂੰ ਕਿਉਂ ਕੀਤਾ ਜਾ ਰਿਹਾ ਹੈ ਅਤੇ ਇਸ ਵਿੱਚ ਕੀ ਕੁਝ ਸ਼ਾਮਲ ਹੋਵੇਗਾ। ਕਿਰਪਾ ਕਰਕੇ ਨਿਮਨਲਿਖਤ ਜਾਣਕਾਰੀ ਨੂੰ ਧਿਆਨ ਨਾਲ ਪੜ੍ਹਨ ਲਈ ਸਮਾਂ ਲਓ ਅਤੇ ਜੇ ਤੁਸੀਂ ਇੱਛਾ ਕਰਦੇ ਹੋ ਤਾਂ ਆਪਣੇ ਦੋਸਤਾਂ, ਰਿਸ਼ਤੇਦਾਰਾਂ ਜਾਂ ਤੁਹਾਡੇ ਪਰਿਵਾਰਕ ਡਾਕਟਰ ਨਾਲ ਵਿਚਾਰ-ਵਟਾਂਦਰਾ ਕਰੋ। ਜੇ ਕੋਈ ਅਜਿਹੀ ਚੀਜ਼ ਹੈ ਜੋ ਤੁਹਾਨੂੰ ਸਪੱਸ਼ਟ ਨਹੀਂ ਹੈ ਜਾਂ ਜੇ ਤੁਸੀਂ ਅਧਿਐਨ ਬਾਰੇ ਵਧੇਰੇ ਜਾਣਨਾ ਚਾਹੋਂਗੇ ਤਾਂ ਸਾਨੂੰ ਪੁੱਛੋ। ਕਰਾਸ ਓਵਰ ਕਲੀਨਿਕੀ ਕੰਟਰੋਲ ਅਧਿਐਨ

1. ਅਧਿਐਨ ਦਾ ਮਕਸਦ ਕੀ ਹੈ? T1D ਮਰੀਜ਼ਾਂ ਵਿੱਚ 3 ਮਹੀਨਿਆਂ ਦੇ ਅੰਤ 'ਤੇ ਗਲਾਈਸੀਮਿਕ ਪ੍ਰੋਫਾਈਲ ਵਿੱਚ ਸੁਧਾਰ 'ਤੇ rt-CGM ਬਨਾਮ is-CGM ਦੀ ਅਸਰਦਾਇਕਤਾ ਦੀ ਤੁਲਨਾ ਕਰਨ ਲਈ

2. ਅਧਿਐਨ ਦੀ ਉਮੀਦ ਕੀਤੀ ਜਾਂਦੀ ਮਿਆਦ ਕੀ ਹੈ?

ਅਧਿਐਨ ਵਾਸਤੇ ਉਮੀਦ ਕੀਤੀ ਜਾਂਦੀ ਮਿਆਦ 6 ਮਹੀਨੇ ਹੈ

3. ਮੈਨੂੰ ਕਿਉਂ ਚੁਣਿਆ ਗਿਆ ਹੈ: ਤੁਹਾਨੂੰ ਟਾਈਪ 1 ਡਾਇਬਿਟੀਜ਼ ਮੈਲੀਟਸ ਤੋਂ ਪੀੜਤ ਮਰੀਜ਼ ਵਜੋਂ ਚੁਣਿਆ ਗਿਆ ਹੈ।

4 . ਇਸ ਖੋਜ ਤੋਂ ਕੀ ਲਾਭ ਹਨ?

ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਤੋਂ ਬਾਅਦ, ਤੁਸੀਂ ਕਾਰਬੋਹਾਈਡਰੇਟ ਦੀ ਗਿਣਤੀ ਕਰਨ ਦੇ ਯੋਗ ਹੋਵੋਗੇ ਅਤੇ ਤੁਹਾਡੀ ਭੋਜਨ ਸਮੱਗਰੀ ਅਤੇ ਭੋਜਨ ਤੋਂ ਪਹਿਲਾਂ ਦੇ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ ਮੁੱਲਾਂ ਦੇ ਅਨੁਸਾਰ ਇਨਸੁਲਿਨ ਖੁਰਾਕਾਂ ਨੂੰ ਅਨੁਕੂਲਿਤ ਕਰ ਸਕੋਗੇ ਜੋ ਤੁਹਾਡੇ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ ਨਿਯੰਤਰਣ ਨਾਲ ਕਿਸੇ ਵੀ ਸਮਝੌਤਾ ਕੀਤੇ ਬਿਨਾਂ ਤੁਹਾਡੇ ਭੋਜਨ ਦੀ ਲਚਕਤਾ ਵਿੱਚ ਸੁਧਾਰ ਕਰੇਗਾ। ਇਸ ਤੋਂ ਇਲਾਵਾ, ਇਸ ਅਧਿਐਨ ਵਿੱਚ 3 ਸਮੂਹ ਹੋਣਗੇ ਅਤੇ ਜੇਕਰ ਤੁਸੀਂ ਦੋ CGMS ਸਮੂਹਾਂ ਵਿੱਚੋਂ ਇੱਕ ਵਿੱਚ ਬੇਤਰਤੀਬ ਹੋ ਜਾਂਦੇ ਹੋ, ਤਾਂ ਤੁਹਾਨੂੰ CGMS ਪ੍ਰਦਾਨ ਕੀਤਾ ਜਾਵੇਗਾ ਅਤੇ ਇਸ ਤਕਨਾਲੋਜੀ ਦੁਆਰਾ ਤੁਹਾਡੇ ਭੋਜਨ ਦੇ ਪੈਟਰਨ ਅਤੇ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ ਦੇ ਉਤਰਾਅ-ਚੜ੍ਹਾਅ ਦਾ ਵਿਸ਼ਲੇਸ਼ਣ ਕੀਤਾ ਜਾਵੇਗਾ ਅਤੇ ਤੁਹਾਡੀ ਇਨਸੁਲਿਨ ਦੀਆਂ ਖੁਰਾਕਾਂ ਨੂੰ ਸੋਧਿਆ ਜਾਵੇਗਾ। ਉਸ ਅਨੁਸਾਰ। ਜੇਕਰ ਤੁਸੀਂ SMBG ਸਮੂਹ ਵਿੱਚ ਬੇਤਰਤੀਬ ਹੋ ਗਏ ਹੋ, ਤਾਂ ਤੁਸੀਂ ਇੱਕ ਮਾਹਰ ਦੀ ਨਜ਼ਦੀਕੀ ਨਿਗਰਾਨੀ ਅਤੇ ਨਿਗਰਾਨੀ ਹੇਠ ਹੋਵੋਗੇ ਅਤੇ ਤੁਹਾਡੀ ਇਨਸੁਲਿਨ ਦੀਆਂ ਖੁਰਾਕਾਂ ਨੂੰ ਦੇਖਭਾਲ ਦੇ ਮਿਆਰ ਅਨੁਸਾਰ ਸੋਧਿਆ ਜਾਵੇਗਾ। ਕਿਸੇ ਵੀ ਸਮੂਹ ਵਿੱਚ ਬੇਤਰਤੀਬੀ ਹੋਣ ਦੇ ਬਾਵਜੂਦ, ਇਸ ਅਧਿਐਨ ਦੌਰਾਨ ਤੁਹਾਡੇ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ ਨਿਯੰਤਰਣ ਵਿੱਚ ਸੁਧਾਰ ਦੀ ਉਮੀਦ ਕੀਤੀ ਜਾਂਦੀ ਹੈ।

ਇਸ ਖੋਜ ਦੁਆਰਾ ਅਸੀਂ ਇਹ ਅਨੁਮਾਨ ਲਗਾ ਰਹੇ ਹਾਂ ਕਿ CGMS ਦੀ ਸਿਰਫ 2 ਹਫਤਿਆਂ ਦੀ ਵਰਤੋਂ ਤੁਹਾਡੇ ਗਲਾਈਸੈਮਿਕ ਪੈਟਰਨਾਂ ਨੂੰ ਉਜਾਗਰ ਕਰਨ ਲਈ ਕਾਫੀ ਹੈ, ਜੋ ਕਿ ਲਾਗਤ ਪ੍ਰਭਾਵਸ਼ਾਲੀ ਹੈ ਅਤੇ 2 ਹਫਤਿਆਂ ਦੀ CGMS ਰਿਪੋਰਟ ਦੇ ਵਿਸ਼ਲੇਸ਼ਣ ਦੁਆਰਾ ਤੁਹਾਡੇ ਇਲਾਜ ਪ੍ਰਣਾਲੀ ਵਿੱਚ ਕੀਤੇ ਗਏ ਵਿਵਹਾਰਿਕ ਬਦਲਾਅ ਅਤੇ ਉਪਚਾਰਕ ਤਬਦੀਲੀਆਂ 'ਤੇ ਪ੍ਰਭਾਵ ਪਾਏਗੀ। ਤੁਹਾਡੇ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ ਨਿਯੰਤਰਣ ਜਿਵੇਂ ਕਿ ਤੁਹਾਡੇ HbA1c ਵਿੱਚ 3 ਮਹੀਨਿਆਂ ਵਿੱਚ ਪ੍ਰਤੀਬਿੰਬਤ ਹੁੰਦਾ ਹੈ। ਜ਼ਿਆਦਾਤਰ ਅਧਿਐਨਾਂ ਵਿੱਚ CGMS ਦੀ ਨਿਰੰਤਰ ਵਰਤੋਂ ਕੀਤੀ ਗਈ ਹੈ ਜੋ ਸਾਡੇ ਦੇਸ਼ ਵਿੱਚ ਵਿਹਾਰਕ ਨਹੀਂ ਹੈ।

5. ਕੀ ਮੈਨੂੰ ਹਿੱਸਾ ਲੈਣਾ ਪਵੇਗਾ?

ਇਹ ਤੁਹਾਡੇ 'ਤੇ ਨਿਰਭਰ ਕਰਦਾ ਹੈ ਕਿ ਤੁਸੀਂ ਹਿੱਸਾ ਲੈਣਾ ਹੈ ਜਾਂ ਨਹੀਂ? ਜੇਕਰ ਤੁਸੀਂ ਹਿੱਸਾ ਲੈਣ ਦਾ ਫੈਸਲਾ ਕਰਦੇ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਰੱਖਣ ਲਈ ਇਹ ਜਾਣਕਾਰੀ ਸ਼ੀਟ ਦਿੱਤੀ ਜਾਵੇਗੀ ਅਤੇ ਇੱਕ ਸਹਿਮਤੀ ਫਾਰਮ 'ਤੇ ਦਸਤਖਤ ਕਰਨ ਲਈ ਕਿਹਾ ਜਾਵੇਗਾ। ਜੇਕਰ ਤੁਸੀਂ ਹਿੱਸਾ ਲੈਣ ਦਾ ਫੈਸਲਾ ਕਰਦੇ ਹੋ ਤਾਂ ਤੁਸੀਂ ਬਿਨਾਂ ਕਾਰਨ ਦੱਸੇ ਕਿਸੇ ਵੀ ਸਮੇਂ ਵਾਪਸ ਲੈਣ ਲਈ ਆਜ਼ਾਦ ਹੋ। ਭਾਵੇਂ ਤੁਸੀਂ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਹਿੱਸਾ ਨਾ ਲੈਣ ਦਾ ਫੈਸਲਾ ਕਰਦੇ ਹੋ, ਇਹ ਤੁਹਾਨੂੰ ਪ੍ਰਾਪਤ ਦੇਖਭਾਲ ਦੇ ਮਿਆਰ ਨੂੰ ਪ੍ਰਭਾਵਤ ਨਹੀਂ ਕਰੇਗਾ।

6. ਜੇ ਮੈਂ ਹਿੱਸਾ ਲਵਾਂ ਤਾਂ ਮੇਰੇ ਨਾਲ ਕੀ ਹੋਵੇਗਾ?
ਤੁਹਾਨੂੰ ਸਹਿਮਤੀ 'ਤੇ ਦਸਤਖਤ ਕਰਨੇ ਪੈਣਗੇ। ਤੁਹਾਡੀ ਸਰੀਰਕ ਜਾਂਚ ਕੀਤੀ ਜਾਵੇਗੀ। ਤੁਹਾਨੂੰ ਸਮੇਂ-ਸਮੇਂ 'ਤੇ ਖੂਨ ਦੇ ਨਮੂਨੇ ਦੇਣੇ ਪੈਂਦੇ ਹਨ ਅਤੇ ਤੁਹਾਨੂੰ rt-CGMS ਜਾਂ is-CGMS ਗਰੁੱਪਾਂ ਵਿੱਚ ਰੱਖਿਆ ਜਾ ਸਕਦਾ ਹੈ। T1D ਦਾ ਮਿਆਰੀ ਇਲਾਜ ਕਿਸੇ ਵੀ ਸਮੂਹ ਵਿੱਚ ਬੇਤਰਤੀਬੇਕਰਨ ਦੀ ਪਰਵਾਹ ਕੀਤੇ ਬਿਨਾਂ ਪ੍ਰਦਾਨ ਕੀਤਾ ਜਾਵੇਗਾ।

7. ਤੁਹਾਡੇ ਲਈ ਕਿਹੜੇ ਵਿਕਲਪ ਉਪਲਬਧ ਹਨ?
ਇਹ ਇੱਕ ਡਰੱਗ ਟ੍ਰਾਇਲ ਨਹੀਂ ਹੈ ਅਤੇ ਅਸੀਂ ਸਿਰਫ਼ CGMS ਦੁਆਰਾ ਤੁਹਾਡੇ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ ਦੇ ਪੱਧਰਾਂ ਦੀ ਨਿਗਰਾਨੀ ਕਰ ਰਹੇ ਹਾਂ, ਜੇਕਰ ਤੁਸੀਂ ਇਸ ਟ੍ਰਾਇਲ ਵਿੱਚ ਹਿੱਸਾ ਨਹੀਂ ਲੈਣਾ ਚਾਹੁੰਦੇ ਹੋ ਤਾਂ ਤੁਸੀਂ ਮਲਟੀਪਲ ਫਿੰਗਰ ਪ੍ਰਿਕਸ ਦੁਆਰਾ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ ਦੀ ਸਵੈ ਨਿਗਰਾਨੀ ਦੀ ਵਰਤੋਂ ਕਰ ਸਕਦੇ ਹੋ ਜਿਵੇਂ ਕਿ ਪ੍ਰਬੰਧਨ ਲਈ ਦੇਖਭਾਲ ਦਾ ਮਿਆਰ ਹੈ। ਟਾਈਪ 1 ਸ਼ੂਗਰ ਦੀ.

8. ਅਧਿਐਨ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣ ਦੇ ਸੰਭਾਵੀ ਜੋਖਮ ਕੀ ਹਨ?
ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਲਗਭਗ ਕੋਈ ਜੋਖਮ ਸ਼ਾਮਲ ਨਹੀਂ ਹੈ ਕਿਉਂਕਿ ਸਿਰਫ ਖੂਨ ਦੇ ਨਮੂਨੇ ਅਤੇ ਗਲੂਕੋਜ਼ ਪ੍ਰੋਫਾਈਲ ਲਈ CGMS ਅਤੇ SMBG ਹੀ ਕੀਤੇ ਜਾਣਗੇ ਜੋ T1D ਵਿੱਚ ਦੇਖਭਾਲ ਦਾ ਆਮ ਮਿਆਰ ਹੈ। ਸਾਡੇ ਅਧਿਐਨ ਦੌਰਾਨ ਤੁਹਾਡੀ ਸਖ਼ਤ ਨਿਗਰਾਨੀ ਕੀਤੀ ਜਾਵੇਗੀ
9. ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਇਲਾਜ ਦਾ ਸਮਾਂ ਕੀ ਹੋਵੇਗਾ?
ਅਧਿਐਨ ਵਿੱਚ 80 ਭਾਗੀਦਾਰ ਸ਼ਾਮਲ ਹੋਣਗੇ ਅਤੇ ਤੁਹਾਨੂੰ ਕੰਪਿਊਟਰ ਦੁਆਰਾ ਤਿਆਰ ਕੀਤੀ ਬੇਤਰਤੀਬ ਨੰਬਰ ਸੂਚੀ ਦੀ ਵਰਤੋਂ ਕਰਕੇ rt-CGMS, is-CGMS ਜਾਂ SMBG ਆਰਮ ਵਿੱਚ ਬੇਤਰਤੀਬ ਕੀਤਾ ਜਾਵੇਗਾ। 2 ਹਫਤਿਆਂ ਦੀ ਸ਼ੁਰੂਆਤੀ ਸਿਖਲਾਈ 3 ਸਮੂਹਾਂ ਵਿੱਚੋਂ ਹਰੇਕ ਵਿੱਚ ਸਾਰੇ ਦਾਖਲ ਮਰੀਜ਼ਾਂ ਲਈ ਬਿਮਾਰੀ ਬਾਰੇ ਖੁਦ, ICR, ISF, ਕਾਰਬੋਹਾਈਡਰੇਟ ਦੀ ਗਿਣਤੀ ਅਤੇ ਇਹਨਾਂ ਮਾਪਦੰਡਾਂ ਦੇ ਅਧਾਰ ਤੇ ਬੋਲਸ ਖੁਰਾਕ ਦੀ ਵਿਵਸਥਾ ਪ੍ਰੀਮੀਅਲ ਬੋਲਸ ਲਈ ਕੀਤੀ ਜਾਵੇਗੀ। ਜੇਕਰ ਤੁਸੀਂ rt-CGM ਗਰੁੱਪ ਵਿੱਚ ਰੈਂਡਮਾਈਜ਼ ਹੋ ਗਏ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ 2 ਹਫ਼ਤਿਆਂ ਲਈ rt-CGM Medtronic CGMS 'ਤੇ ਰੱਖਿਆ ਜਾਵੇਗਾ; ਜੇਕਰ CGM ਗਰੁੱਪ ਵਿੱਚ ਹੈ, ਤਾਂ ਤੁਹਾਨੂੰ 2 ਹਫ਼ਤਿਆਂ ਲਈ Abott Libre Flash ਸਿਸਟਮ ਦਿੱਤਾ ਜਾਵੇਗਾ ਅਤੇ ਜੇਕਰ SMBG ਗਰੁੱਪ ਵਿੱਚ ਹੈ, ਤਾਂ ਤੁਸੀਂ ਨਿਗਰਾਨੀ ਕਰੋਗੇ। ਦਿਨ ਵਿੱਚ ਘੱਟੋ-ਘੱਟ 4 ਵਾਰ ਇੱਕ ਤੋਂ ਵੱਧ ਉਂਗਲਾਂ ਨਾਲ ਖੂਨ ਵਿੱਚ ਗਲੂਕੋਜ਼ - ਨਾਸ਼ਤੇ ਤੋਂ ਪਹਿਲਾਂ, ਦੁਪਹਿਰ ਦੇ ਖਾਣੇ ਤੋਂ

ਪਹਿਲਾਂ, ਅਤੇ ਰਾਤ ਦੇ ਖਾਣੇ ਤੋਂ ਪਹਿਲਾਂ ਅਤੇ ਭੋਜਨ ਤੋਂ ਬਾਅਦ (ਰੋਟੇਸ਼ਨਲ ਆਧਾਰ 'ਤੇ ਕਿਸੇ ਵੀ ਇੱਕ ਭੋਜਨ ਤੋਂ ਬਾਅਦ) ਹਫ਼ਤੇ ਦੇ ਦਿਨ ਅਤੇ 7 ਪੁਆਇੰਟ ਪ੍ਰੋਫਾਈਲ ਹਫ਼ਤੇ ਵਿੱਚ ਇੱਕ ਵਾਰ ਐਤਵਾਰ ਨੂੰ। 3 ਮਹੀਨਿਆਂ ਬਾਅਦ, ਜੇਕਰ ਤੁਸੀਂ ਕਿਸੇ ਵੀ CGMS ਸਮੂਹ ਵਿੱਚ ਸੀ, ਤਾਂ ਤੁਹਾਨੂੰ ਦੂਜੇ CGMS ਸਮੂਹ ਵਿੱਚ ਬਦਲ ਦਿੱਤਾ ਜਾਵੇਗਾ, ਹਾਲਾਂਕਿ, ਜੇਕਰ ਤੁਸੀਂ SMBG ਸਮੂਹ ਵਿੱਚ ਸੀ, ਤਾਂ ਤੁਸੀਂ ਇਸ ਅਧਿਐਨ ਦੇ ਅੰਤ ਤੱਕ ਉਸ ਸਮੂਹ ਵਿੱਚ ਬਣੇ ਰਹੋਗੇ।

10. ਜਾਂਚ ਲਈ ਕਿੰਨਾ ਖੂਨ ਲਿਆ ਜਾਵੇਗਾ ਅਤੇ ਕਿਹੜੇ ਸਮੇਂ 'ਤੇ ਬਿੰਦੂ ਹਨ?
ਸਿਖਲਾਈ ਪੜਾਅ (2 ਹਫ਼ਤੇ) ਦੇ ਅੰਤ ਤੋਂ ਬਾਅਦ 2ml ਖੂਨ ਲਿਆ ਜਾਵੇਗਾ, ਫਿਰ CGMS ਡਿਵਾਈਸ ਐਪਲੀਕੇਸ਼ਨ (4 ਹਫ਼ਤੇ) ਦੇ ਅੰਤ ਤੋਂ ਬਾਅਦ ਅਤੇ ਤਿੰਨ ਮਹੀਨੇ ਅਤੇ ਸਾਢੇ ਤਿੰਨ ਮਹੀਨੇ ਅਤੇ ਅੰਤ ਵਿੱਚ 6 ਮਹੀਨੇ 2 ਹਫ਼ਤੇ (ਕੁੱਲ 8 ਮਿ.ਲੀ.) ਹਰੇਕ ਮਰੀਜ਼ ਲਈ 6 ਮਹੀਨਿਆਂ ਦੀ ਮਿਆਦ ਵਿੱਚ ਖੂਨ ਲਿਆ ਜਾਵੇਗਾ)" (CGMS ਸਮੂਹ ਵਿੱਚ ਕੁੱਲ ਚਾਰ ਵਾਰ)। SMBG ਗਰੁੱਪ ਵਿੱਚ ਸਿਖਲਾਈ ਪੜਾਅ (2 ਹਫ਼ਤਿਆਂ) ਦੇ ਅੰਤ ਤੋਂ ਬਾਅਦ, 3 ਮਹੀਨੇ ਅਤੇ 2 ਹਫ਼ਤੇ ਅਤੇ ਅੰਤ ਵਿੱਚ 6 ਮਹੀਨੇ 2 ਹਫ਼ਤੇ (ਹਰੇਕ ਮਰੀਜ਼ ਲਈ 6 ਮਹੀਨਿਆਂ ਦੀ ਮਿਆਦ ਵਿੱਚ ਕੁੱਲ 6 ਮਿਲੀਲੀਟਰ ਖੂਨ) ਲਿਆ ਜਾਵੇਗਾ; ਅਧਿਐਨ ਦੌਰਾਨ ਕੁੱਲ 3 ਵਾਰ.

11. ਕੀ ਇਸ ਅਧਿਐਨ ਦੇ ਮੇਰੇ ਬੋਲਣ ਵਾਲੇ ਹਿੱਸੇ ਨੂੰ ਗੁਪਤ ਰੱਖਿਆ ਜਾਵੇਗਾ?
ਕੋਰਸ ਦੇ ਅਧਿਐਨ ਦੌਰਾਨ ਤੁਹਾਡੇ ਬਾਰੇ ਇਕੱਠੀ ਕੀਤੀ ਗਈ ਸਾਰੀ ਜਾਣਕਾਰੀ ਨੂੰ ਗੁਪਤ ਰੱਖਿਆ ਜਾਵੇਗਾ।

12. ਮੁਕੱਦਮੇ ਨਾਲ ਸਬੰਧਤ ਸੱਟ ਦੇ ਮਾਮਲੇ ਵਿੱਚ ਕੀ ਮੁਆਵਜ਼ਾ ਅਤੇ ਜਾਂ ਇਲਾਜ ਉਪਲਬਧ ਹਨ?
ਅਸੀਂ ਇੱਥੇ ਜੋ ਦਖਲਅੰਦਾਜ਼ੀ ਕਰ ਰਹੇ ਹਾਂ ਉਹ 14 ਦਿਨਾਂ ਲਈ ਨਿਰੰਤਰ ਗਲੂਕੋਜ਼ ਨਿਗਰਾਨੀ ਪ੍ਰਣਾਲੀ ਦੀ ਵਰਤੋਂ ਹੈ ਜੋ ਕਿ ਟਾਈਪ-1 ਡਾਇਬੀਟੀਜ਼ ਮਲੇਟਸ ਲਈ ਦੇਖਭਾਲ ਦਾ ਮਿਆਰ ਹੈ ਜਿਵੇਂ ਕਿ ਵੱਖ-ਵੱਖ ਦਿਸ਼ਾ-ਨਿਰਦੇਸ਼ਾਂ (ਰੇਫ ADA 2022) ਦੁਆਰਾ ਵਕਾਲਤ ਕੀਤੀ ਗਈ ਹੈ, ਸਾਰੇ ਮਰੀਜ਼ਾਂ ਨੂੰ ਦੇਖਭਾਲ ਦੇ ਇਲਾਜ ਦੇ ਮਿਆਰ (ਇਨਸੁਲਿਨ) ਪ੍ਰਾਪਤ ਹੋਣਗੇ। ਟਾਈਪ 1 ਸ਼ੂਗਰ ਲਈ) ਅਤੇ ਕੋਈ ਨਵਾਂ ਇਲਾਜ ਪੇਸ਼ ਨਹੀਂ ਕੀਤਾ ਜਾ ਰਿਹਾ ਹੈ। ਇਸ ਤੋਂ ਬਾਅਦ, ਇਹ ਉਮੀਦ ਨਹੀਂ ਕੀਤੀ ਜਾਂਦੀ ਹੈ ਕਿ ਅਧਿਐਨ ਵਿਚ ਵਿਸ਼ੇਸ਼ ਦਖਲਅੰਦਾਜ਼ੀ ਦੇ ਕਾਰਨ ਕੋਈ ਵੀ ਮਰੀਜ਼ ਕੋਈ ਉਲਟ ਘਟਨਾ ਪੈਦਾ ਕਰੇਗਾ ਕਿਉਂਕਿ ਅਸੀਂ ਸਿਰਫ ਉਨ੍ਹਾਂ ਦੇ ਗਲੂਕੋਜ਼ ਦੇ ਪੱਧਰ ਦੀ ਨਿਗਰਾਨੀ ਕਰ ਰਹੇ ਹਾਂ। ਹਾਲਾਂਕਿ ਜੇਕਰ ਕੋਈ ਮਰੀਜ਼ ਗੰਭੀਰ ਹਾਈਪੋਗਲਾਈਸੀਮੀਆ

(ਜੋ ਕਿ ਇਨਸੁਲਿਨ ਥੈਰੇਪੀ 'ਤੇ ਟਾਈਪ 1 ਸ਼ੂਗਰ ਦੇ ਕਿਸੇ ਵੀ ਵਿਅਕਤੀਗਤ ਮਰੀਜ਼ ਵਿੱਚ ਹੋ ਸਕਦਾ ਹੈ) ਸਮੇਤ ਹਾਈਪੋਗਲਾਈਸੀਮੀਆ ਵਿਕਸਿਤ ਕਰਦਾ ਹੈ, ਤਾਂ ਲੋੜ ਪੈਣ 'ਤੇ ਹਸਪਤਾਲ ਵਿੱਚ ਦਾਖਲੇ ਸਮੇਤ ਰੁਟੀਨ ਕਲੀਨਿਕਲ ਦੇਖਭਾਲ ਦੇ ਅਨੁਸਾਰ ਪ੍ਰਬੰਧਨ ਕੀਤਾ ਜਾਵੇਗਾ।

13. ਕੀ ਭਾਗੀਦਾਰਾਂ ਨੂੰ ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਹਿੱਸਾ ਲੈਣ ਲਈ ਭੁਗਤਾਨ ਕੀਤਾ ਜਾਂਦਾ ਹੈ?
ਭਾਗੀਦਾਰਾਂ ਨੂੰ ਨਿਯਮਾਂ ਅਨੁਸਾਰ ਉਹਨਾਂ ਦੇ ਅਧਿਐਨ ਸੰਬੰਧੀ ਵਾਧੂ ਮੁਲਾਕਾਤਾਂ ਲਈ ਅਦਾਇਗੀ ਕੀਤੀ ਜਾਵੇਗੀ। ਇਸ ਤੋਂ ਇਲਾਵਾ ਉਨ੍ਹਾਂ ਨੂੰ ਕੋਈ ਵਾਧੂ ਪੈਸਾ ਨਹੀਂ ਦਿੱਤਾ ਜਾਵੇਗਾ। ਇਸ ਅਧਿਐਨ ਵਿੱਚ ਭਾਗ ਲੈਣ ਲਈ ਭਾਗੀਦਾਰਾਂ ਦੁਆਰਾ ਕੋਈ ਵਾਧੂ ਖਰਚਾ ਨਹੀਂ ਚੁੱਕਣਾ ਪਵੇਗਾ।

14. ਅਧਿਐਨ ਦੇ ਨਤੀਜਿਆਂ ਨਾਲ ਕੀ ਕੀਤਾ ਜਾਵੇਗਾ?
ਖੋਜ ਦੇ ਨਤੀਜੇ ਪ੍ਰਕਾਸ਼ਿਤ ਕੀਤੇ ਜਾ ਸਕਦੇ ਹਨ। ਅਸੀਂ ਤੁਹਾਨੂੰ ਭਰੋਸਾ ਦਿਵਾਉਂਦੇ ਹਾਂ ਕਿ ਕਿਸੇ ਵੀ ਰਿਪੋਰਟ/ਪ੍ਰਕਾਸ਼ਨ ਵਿੱਚ ਤੁਹਾਡੀ ਪਛਾਣ ਨਾਂ ਨਾਲ ਨਹੀਂ ਕੀਤੀ ਜਾਵੇਗੀ।

15. ਖੋਜ ਦਾ ਆਯੋਜਨ ਕੌਣ ਕਰ ਰਿਹਾ ਹੈ?
ਐਂਡੋਕਰੀਨੋਲੋਜੀ ਵਿਭਾਗ, ਪੀਜੀਆਈਐਮਈਆਰ, ਚੰਡੀਗੜ੍ਹ ਇਸ ਖੋਜ ਦਾ ਆਯੋਜਨ ਕਰ ਰਿਹਾ ਹੈ

16. ਇਸ ਅਧਿਐਨ ਦੀ ਸਮੀਖਿਆ ਕਿਸਨੇ ਕੀਤੀ ਹੈ?
ਸੰਸਥਾ ਦੀ ਨੈਤਿਕਤਾ ਕਮੇਟੀ ਅਧਿਐਨ ਦੀ ਸਮੀਖਿਆ ਕਰੇਗੀ।

17. ਜੇਕਰ ਕਿਸੇ ਸਵਾਲ ਜਾਂ ਸ਼ਿਕਾਇਤ ਲਈ ਮੈਂ ਕਿਸ ਨਾਲ ਸੰਪਰਕ ਕਰ ਸਕਦਾ/ਸਕਦੀ ਹਾਂ?
ਤੁਸੀਂ ਹੇਠਾਂ ਦਿੱਤੇ ਲੋਕਾਂ ਨਾਲ ਸੰਪਰਕ ਕਰ ਸਕਦੇ ਹੋ:
1. ਪ੍ਰਿੰਸੀਪਲ ਇਨਵੈਸਟੀਗੇਟਰ- ਡਾ. ਸੰਜੇ ਕੁਮਾਰ ਭੱਦਾ, ਵਿਭਾਗ ਦੇ ਮੁਖੀ, ਐਂਡੋਕਰੀਨੋਲੋਜੀ ਵਿਭਾਗ ਦਾ ਕਮਰਾ ਨੰਬਰ 1, ਗਰਾਊਂਡ ਫਲੋਰ, ਨਹਿਰੂ ਹਸਪਤਾਲ ਐਕਸਟੈਂਸ਼ਨ, ਪੀਜੀਆਈਐਮਈਆਰ, ਚੰਡੀਗੜ੍ਹ-160012, ਫ਼ੋਨ ਨੰਬਰ: +919876602448

2. ਇੰਸਟੀਚਿਊਟ ਐਥਿਕਸ ਕਮੇਟੀ, ਪੀ.ਜੀ.ਆਈ.ਐਮ.ਈ.ਆਰ.- 6ਵੀਂ ਮੰਜ਼ਿਲ ਪੀ.ਐਨ.ਚੁਟਾਨੀ ਬਲਾਕ, ਚੰਡੀਗੜ੍ਹ- 160012, ਫ਼ੋਨ ਨੰਬਰ: 0172-2755266।