Real time vs. Flash glucose monitoring in type 1 diabetes - a cross-over trial

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To compare the effects on glycemic control, patient reported outcomes (PRO) and experiences (PRE) of rt-CGM with FGM in a real-life outpatient setting among persons with T1D.

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON51332

Source
ToetsingOnline

Brief title
RT-CGM vs. FGM in T1D

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Dit is een investigator initiated onderzoek. Het UMCG verstrekt 55.000. Health Holland verstrekt een PPP-beurs (50.000);Menarini verstrekt materialen en 75.000 euro,Menarini

Intervention

Keyword: Continuous glucose sensor, Flash glucose sensor, Type 1 diabetes mellitus

Outcome measures

Primary outcome

Primary endpoint is the difference in percentage of time in the hypoglycemic (defined as glucose < 3.9 mmol/l) range, measured by blinded CGM during the last week of each treatment phase, between FGM and rt-CGM.

Secondary outcome

Secondary outcomes include changes in glucose control, sensor performance, changes in clinical parameters, PROs and PREs (including health related quality of life, treatment satisfaction, fear of hypoglycemia, diabetes distress and patient preference) during and between both treatment phases.

Study description

Background summary

Continuous glucose monitoring (CGM) devices measure glucose concentrations continuously in the interstitial fluid. CGM currently is considered usual care for the majority of persons with type 1 diabetes (T1D) and two methods are available: real-time CGM (rt-CGM) and intermittent / flash glucose monitoring (FGM). While rt-CGM continuously provides data on glucose concentrations and (anticipating) alarms at pre-set glucose values, FGM only provides data when end-users actively read out (scan) their device and provides alarms below a pre-set value. Previous studies between both methods demonstrated better outcomes of rt-CGM as compared to FGM, however most of these studies were performed with FGM without alarm function and did not include patient reported outcomes (PRO). Given the wide-spread use of both methods, it is of importance to compare the effects of rt-CGM and FGM.

Study objective

To compare the effects on glycemic control, patient reported outcomes (PRO) and

experiences (PRE) of rt-CGM with FGM in a real-life outpatient setting among persons with T1D.

Study design

Open-label, prospective, randomized, two-period cross-over study during real-life circumstances. The intervention phase is two times 28 days, consecutively. Between the treatment phases is a 7-day wash-out phase. In the last week of each 28-day treatment phase, participants will wear a blinded CGM (ipro-2 CGM, Medtronic CGM), to assess the primary outcome. In this study, GlucoMen® Day CGM (WaveForm Cascade) Continuous Glucose Monitor will be used as method for rt-CGM. For FGM the FreeStyle LibreTM glucose monitor version 2 (Abbott Diabetes Care Witney, UK), with alarms, will be used.

Study burden and risks

During the 63-day study period participants will be asked to wear the different sensors and an activity tracker.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Type 1 diabetes mellitus (as defined by the American Diabetes Association criteria) for >= 6 months
- Intensive insulin regimen consisting of MDI (basal-bolus with > 3 injections/day) or CSII established for more than 3 months
- Blood glucose control for >= 4 times per day, either using fingerprick measurements, FSL-FGM or rt-CGM established for more than 3 months
- Age 18 to 75 years
- HbA1c < 10.5 % (91 mmol/mol), as determined - Normal hypoglycemia awareness (Gold score < 4)
- Internet and cellular phone coverage
- Dutch writing and speaking proficiency
- Ability to provide oral and written informed consent

Exclusion criteria

- Oral of injected steroid using within the past 3 months
- Pregnancy or planned pregnancy
- Uncontrolled thyroid disease or uncontrolled hypertension
- Poor visual acuity
- Inability or unwillingness to meet the protocol requirements
- Severe cognitive impairment
- Any severe or uncontrolled medical or psychological condition which, in the opinion of the investigator, would compromise the ability to meet protocol requirements.

Study design

Design

Study type:	Observational invasive
Intervention model:	Crossover

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2022
Enrollment:	48
Type:	Anticipated

Medical products/devices used

Generic name:	GlucoMen® Day CGM (WaveForm Cascade) Continuous Glucose Monitor
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-03-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	14-04-2023
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL81576.042.22