Performance of a new real-time continuous glucose monitoring system: a validation study of the idi-CGM in type 1 diabetes

Published: 22-02-2024
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To establish the performance of the idi-CGM system among persons with DM.

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

Summary

ID

NL-OMON56615

Source
ToetsingOnline

Brief title
Validation MySensible idi-CGM

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes mellitus

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Dit is een investigator initiated onderzoek. MySensible voorziet in materialen en een unrestricted grant,MySensible

Intervention

Keyword: Continuous glucose sensors, Diabetes mellitus, Glucose sensor

Outcome measures

Primary outcome

Primary outcome is the accuracy of the idi-CGM

compared to Contour Plus Blue strip capillary measurement results during the

14-day study period.

Secondary outcome

Secondary outcomes include (i) accuracy of the idi-CGM compared to the Dexcom

G6 rt-CGM during the 14-day study period, (ii) accuracy of the idi-CGM during

the standardized meal test and (iii) usability and satisfaction with the

idi-CGM. Accuracy will (primarily) be analysed as according to the guidelines

for Integrated Continuous Glucose Monitoring Approvals (Class II-510(K),

(Parkes) error grid-, bias (including MARD), correlation, stability and Bland-

Altman analysis.

Study description

Background summary

Continuous glucose monitoring (CGM) devices measure glucose concentrations continuously in the interstitial fluid. Accurate glucose measurements are of utmost importance for persons with diabetes mellitus (DM) as they guide management decisions. Sensible Healthcare Systems developed a novel real-time CGM device (rt-CGM), the idi-CGM. This device consists of microneedles (~1 mm), that are less invasive than currently available alternatives, and measures glucose in the dermis.

Study objective

To establish the performance of the idi-CGM system among persons with DM.

Study design

Prospective non-randomized cohort study assessing the performance of the idi-CGM as compared to the gold standard (capillary measurements using Contour Plus Blue monitoring system (Ascencia Diabetes Care) and a commonly used real-time CGM (rt-CGM) device (Dexcom G6). Measurements will be performed during a 14-day study period which includes an in-clinic visit to perform a standardized glucose load test.

Intervention

Patients wear a new device that measures glucose.

Study burden and risks

Participants will be asked to wear two glucose monitoring devices at once and to measure their capillary blood glucose levels at regular intervals (at least 4, but preferably 7 times daily). Furthermore, there is a 2-hour in-hospital standardized glucose challenge test.

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

- presence of type 1 DM;
- age between 18 and 75 years old.

Exclusion criteria

- A history of allergies towards (microneedle) patch substances/adhesive;
- The inability to understand the Dutch language;
- Oral of injected steroid using within the past 3 months
- Pregnancy or planned pregnancy
- Uncontrolled thyroid disease or hypertension
- Poor visual acuity
- Inability or unwillingness to meet the protocol requirements
- 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: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2026
Enrollment:	15
Type:	Anticipated

Medical products/devices used

Generic name:	Idi continue glucose monitoring device
Registration:	No

Ethics review

Approved WMO Date:	22-02-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	30-10-2024
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	NL77715.000.22