Performance of a new real-time continuous glucose monitoring system: a validation study of the Medtrum TouchCare Nano 14 CGM System

Published: 14-08-2023
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To establish the performance of the TouchCare Nano 14 CGM system among persons with DM.

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

Summary

ID

NL-OMON53212

Source
ToetsingOnline

Brief title
Performance of the Medtrum TouchCare Nano 14 CGM system

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. Medtrum voorziet in materialen en een unrestricted grant,Medtrum

Intervention

Keyword: Continous blood glucose measurement, Diabetic Mellitus, Glucose

Outcome measures

Primary outcome

Primary outcome is the accuracy of the TouchCare Nano 14 CGM compared to Contour Plus Bluestrip capillary measurement results during the 14-day study period.

Secondary outcome

Secondary outcomes include (i) accuracy of the TouchCare Nano 14 CGM compared to the FreeStyle Libre 2 CGM during the 14-day study period and (ii) usability and satisfaction with the TouchCare Nano 14 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

The Medtrum TouchCare Nano 14 CGM System is a novel CGM system for interstitial glucose measurements. It uses a small, soft and transcutaneous glucose oxidase* based electrochemical glucose sensor (MD3568) to detect glucose levels in the interstitial fluid every 2 min; this sensor provides information over a period of maximal 14 days. As accurate glucose measurements are of utmost importance for persons with type 1 diabetes mellitus (T1DM), information concerning the

accuracy of this device is of relevance. Since the testing up to now has been performed with the TouchCare Nano Sensor inserted in the upper arm, further testing on performance and accuracy when inserted in another part of the body is also needed.

Study objective

To establish the performance of the TouchCare Nano 14 CGM system among persons with DM.

Study design

Prospective non-randomized cohort study assessing the performance of the TouchCare Nano 14 CGM as compared to capillary measurements using Contour Plus Blue monitoring system (Ascencia Diabetes Care) (traceable to the gold standard glucose Isotope Dilution-Gas Chromatography-Mass Spectrometry (ID-GCMS) and controlled with National Institute of Standards and Technology (NIST) and a commonly used CGM (CGM) device (FreeStyle Libre 2). Measurements will be performed during a 14-day study period.

Study burden and risks

Participants will be asked to wear three glucose monitoring devices at once and to measure their capillary blood glucose levels at regular intervals (at least 4, but preferably 7 times daily).

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

- The inability to understand the Dutch language;
- Poor visual acuity
- Inability or unwillingness to meet the protocol requirements

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-08-2024

Enrollment:	23
Type:	Actual

Medical products/devices used

Generic name:	TouchCare Nano 14 CGM System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-08-2023
Application type:	First submission
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	NL84439.075.23