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

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To establish the accuracy of the Medtrum TouchCare Nano 14 CGM system compared to thecurrent gold standards i.e. established central laboratory technique (the StatStrip Xpress®monitoring system (Nova Biomedical, Waltham, WA), the accuracy of a...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational invasive

Summary

ID

NL-OMON50146

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 onder coordinatie van de afdeling inwendige geneeskunde Isala. Medtrum voorziet in de materialen en kosten voor METC en mensuren worden gedeclareerd.

Intervention

Keyword: Continouos blood glucose measurement, Diabetic Mellitus, Glucose

Outcome measures

Primary outcome

The accuracy of both TouchCare Nano 14 CGMs compared to StatStrip Xpress®

during the 14-day study period.

Secondary outcome

The accuracy of both TouchCare Nano 14 CGMs compared to the FGM-FSL1-CGM and

the StatStrip Xpress readings during the 14-day study period.

Study description

Background summary

Accurate glucose measurements are of utmost importance in the management of type 1 diabetes mellitus (T1DM). These results are used to make decisions concerning insulin dose. Next to self-measurement of blood glucose (SMBG) with finger pricks, continuous glucose measurements (real-time or intermittent/flash) with sensors have emerged as valuable options for glucose estimates. In the past decade, a variety of options for continuous glucose monitoring (CGM) have become available. For many users, this opportunity for continuous and automatically readable glucose readings is a big step forward.

CGM systems measure interstitial fluid glucose levels at rather closely spaced intervals to provide semi-continuous information on glucose levels, allowing identification and signalling of glucose level fluctuations to a degree that cannot be obtained with intermittent capillary blood glucose measurements. While improved glycemic control has been demonstrated with the use of CGM systems, CGM accuracy also remains a challenge; many of the available systems need calibrating at least twice daily to allow a sufficiently reliable correlation between interstitial and capillary glucose results.

Whenever a new CGM device becomes available, it is essential to critically evaluate its accuracy and usability. This also will be necessary for the Medtrum TouchCare Nano 14 CGM System. This system uses a small, soft and transcutaneous glucose oxidase*based electrochemical glucose sensor (MD*JY*006) to detect glucose levels in the interstitial fluid every 2 min over 7 days. It has an one*point calibration algorithm. Independent accuracy assessments of the recently introduced TouchCare A7+ CGM System are scarce, with only one publication up to now (PMID: 28563974).

This study by Zhou et al. was performed among 63 Chinese persons, aged 18-70 years (mean 59 years), with diabetes (10 type 1 and 53 type 2 diabetes), BMI 24.7 kg/m2 and mean HbA1c 8.2 ± 1.7%. The TouchCare CGM system was worn for 7 consecutive days and on a randomized day venous blood samples were collected (in clinic, for 7 h with venous blood collected every 15 min) as comparison to CGM based glucose outcomes. A total op 1678 paired sensor-reference based values were collected from 60 participants. The percentages of sensor values that met the ±10%/10 mg/dL, ±15%/15 mg/dL, ±20%/20 mg/dL, ±30%/30 mg/dL, and ±40%/40 mg/dL deviation criteria were 65.7, 81.5, 90.5% (95% CI: 89.1-91.9%), 96.9 and 98.9%, respectively. The mean absolute relative difference (MARD) was 9.1 (8.9 to 9.2)%. there was no significant difference among the MARDs for the 7 days tested by the analysis of variance. In Clarke Error Grid analysis 99.1% of the paired sensor-reference values fell within zones A and B (89.7% within zone A and 9.4% within zone B). Just 15 (0.9%) paired sensor-reference values fell within clinical risk zone D, which represents *dangerous failure to detect and treat* errors. No paired sensor-reference values fell within zone C or E.

The presently proposed study is designed to further assess the accuracy and usability of the TouchCare Nano 14 CGM system by comparing its scanned sensor results with various standardized capillary reference methods and the results obtained with a flash glucose monitoring system (FGM) in subjects with type 1 diabetes.

Study objective

To establish the accuracy of the Medtrum TouchCare Nano 14 CGM system compared to the
current gold standards i.e. established central laboratory technique (the StatStrip Xpress®
monitoring system (Nova Biomedical, Waltham, WA), the accuracy of a flash glucose monitoring (FGM) system (Free Style Libre) (FGM-FSL).

Study design

This study has a prospective design. Inclusion and study procedures will take place at
the Department of Internal Medicine of the Isala hospital (Zwolle, the

Netherlands).

The overall study duration for each participant will be 14 days. After obtaining informed consent, baseline characteristics (a.o. age, gender, body mass index, waist circumference, diabetes duration, kind of insulin treatment modality, use of other medication) will be collected using a standardized case-record form during the first study visit.

Additionally, both a TouchCare Nano 14 CGM will be inserted in the abdominal wall and the back of one of the upper arms. The FGM-FSL will be inserted in the contralateral upper arm. All device related procedures will performed by one trained investigator.

Out-of-hospital testing
Patients will be instructed to perform at least 4 capillary self-measurements (preferably 7) with the StatStrip Xpress® monitoring system (Nova Biomedical, Waltham, WA).

The preferred testing sequence will be at least upon waking, before lunch, before dinner and at bedtime. It will be recommended to also confirm glucose levels with a capillary measurement in case of (imminent and / or suspected) hypoglycemia, glucose levels changing rapidly, or when symptoms do not match the systems readings. All data available within the report systems will be electronically collected from the source systems

Study burden and risks

A small needle is inserted through the skin and a small probe remains for 14 days. No further risks for the subject

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

Participants will be selected from patients seen at the diabetes outpatient clinics of the Isala hospital, Zwolle and the University Medical Center in Groningen

Exclusion criteria

Main exclusion criteria are the inability to understand the Dutch language and the presence of a severe or unstable medical condition.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start

Enrollment:	30
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	13-08-2020
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL74392.075.20