Performance of the GlucoMen® Day (WaveForm Cascade) Continuous Glucose Monitor (CGM) in daily practice

Published: 13-08-2020 Last updated: 09-04-2024

The primary objective of this study is to establish the performance of the M-CGM asCompared to capillary measurements. As secondary outcomes we will compare theperformance of the M-CGM with current FGM and rt-CGM techniques.

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

Summary

ID

NL-OMON49722

Source ToetsingOnline

Brief title Performance of the GlucoMen® Day Continuous Glucose Monitor

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 Diabetes Research Center Isala;Zwolle. Menarini (Divisie Nederland)

1 - Performance of the GlucoMen® Day (WaveForm Cascade) Continuous Glucose Monitor ... 12-05-2025

voorziet in materialen en een unrestricted grant, Menarini (Nederland)

Intervention

Keyword: Continous blood glucose measurement, Diabetes Mellitus, Glucose

Outcome measures

Primary outcome

The performance of the M-CGM compared to Nova capillary test strip during the

14-day study period.

Secondary outcome

The performance of the M-CGM compared to FGM and rt-CGM

Study description

Background summary

Diabetes therapy requires intensive self-management from patients with diabetes type 1 including at least four times measurement of glucose concentrations and injection of the blood glucose lowering hormone insulin. Each time, patients need to determine their need for insulin, which depends mostly on the actual blood sugar value, anticipated glucose trends, what the patient is going to eat (to be more precise: the amount of carbohydrates in the food), to what extent the patient has performed physical activities in the last couple of days, is going to perform physical exercise in the coming couple of hours, as well as the insulin boluses given recently. Next to these factors, (at least) two other personal factors attenuate the amount of insulin needed: carbohydrate ratio and insulin sensitivity; these factors are personal and can vary over the course of days, and weeks.

Classically, capillary self-measurements with fingerpricks are used to measure glucose concentrations. As this method is painful, prone to errors, time consuming, and does not allow identification of the course of glucose concentrations novel methods to measure glucose have been developed over the last decades. In particular measurement of glucose concentrations in the interstitial fluid has manifested as a viable alternative to capillary measurements. At present, real-time continuous glucose monitoring (rt-CGM) and flash glucose monitoring (FGM) are available as methods for interstitial glucose measurements. Most rt-CGM and FGM methods use glucose oxidase based techniques for measuring glucose, moreover fluorescence based are also available. If used appropriately, with rt-CGM the user often only needs to calibrate the sensor at some time points daily and being able to act and react on alarms preset at certain cut-off points. In contrast, FGM users use a factory-calibrated sensor, which with the currently available version in the Netherlands needs scanning for obtaining the required information.

In recent years, the frequency of use of both FGM and rt-CGM has increased markedly. Also, more device manufacturers have become active. With each introduction of a newly developed device it is imperative to validate such device and assess accuracy, both under strictly controlled circumstances and during normal daily life activities. Recently, the GlucoMen® Day CGM (WaveForm Cascade) Continuous Glucose Monitor (CGM) (in short: Menarini CGM, M-CGM) has been introduced in Europe. The device is CEE certified, but has not been widely introduced yet. Given the importance of reliable glucose measurements in type 1 diabetes management, it is of great importance and direct relevance for end-users that real-life data concerning the performance of the M-CGM become available.

In recent years, our research group has assessed the performance of a variety of capillary blood glucose measurement devices, FGMs and rt-CGMs. Under different conditions, the proposed study would comprise both assessments during normal daily life circumstances and in a controlled outpatient setting. In these Covid-19 times, it is proposed to choose another approach, without personal in-clinic contacts to collect data. It is proposed to assess results of the Nova hand-held capillary glucose meter (from now: Nova) with the M-CGM and the measurement devices (FGM or rt-CGM) normally used by the study participants. This allows a robust and real-life assessment of the performance of the M-CGM.

Study objective

The primary objective of this study is to establish the performance of the M-CGM as Compared to capillary measurements. As secondary outcomes we will compare the performance of the M-CGM with current FGM and rt-CGM techniques.

Study design

This is a 14-day, prospective, observational study during real-life circumstances.

Study burden and risks

A small needle is insered through the skin and a small probe remains for 14

days. No futher risks for the subjects

Contacts

Public Isala Klinieken

Dr. van Heesweg 2 Zwolle 8025AB NL **Scientific** Isala Klinieken

Dr. van Heesweg 2 Zwolle 8025AB NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

Subjects with type 1 diabetes mellitus, using insulin either by MDI or CSII. Ability to provide oral and written informed consent

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:	Pending
Start date (anticipated):	01-08-2020
Enrollment:	20
Туре:	Anticipated

Medical products/devices used

Generic name:	GlucoMen® Day (WaveForm Cascade) Continuous Glucose Monitor (CGM)
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 CCMO **ID** NL74404.075.20