Performance of the Eversense vs the Free Style Libre Flash Monitor in (before, during and after) strenuous and extreme exercise conditions in subjects with diabetes

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To assess accuracy of ECGM vs FLFM in 25 subjects with diabetes before, during a 6 day mountainbike tour and after the tour in the Sierra NevadaTo assess the (differences in) time in hypo-, normo- ,and hyperglycemia (expressed in minutes per day…

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

Summary

ID

NL-OMON45979

Source
ToetsingOnline

Brief title
ECGM vs FLFM during exercise

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Diabetescentrum
Source(s) of monetary or material Support: studie wordt gesponsord door de firma Roche

Intervention

Keyword: Blood glucose, Continuous Glucose Registration, Diabetes

Outcome measures

Primary outcome

Parkes Error grids (ISO15197:2013)

Secondary outcome

A: Time in hypoglycemia comparing FLFM and GCCGM.

B: Time in normo- and in hyperglycemia, again comparing both devices.

C: satisfaction with and usability of the devices in the 6-day challenge

period.

D: MAD and MARD comparing FLFM, GCCGM and capillary measurements

Study description

Background summary

In subjects with diabetes, adequate to good metabolic control is necessary for a variety of reasons. In active subjects who perform exercising and sports activities, adequate glucose control, including prevention of hypo- and hyperglycemias, would allow good performance. This will even more so the case when the sports activity is going to the strenuous and extreme.
One variation on earlier continue glucose monitoring (CGM) is FreeStyle Libre Flash Monitor (FLFM) an improved easiness of use and practical applicability. Relying on a CGM device implicates the assumption, that the device will be accurate and reliable. Another device registering glucose continuously, is entering the market: Eversense (Senseonics Inc.) (ECGM).
For assessment of the accuracy and reliability of both the FLFM and the ECGM under strenuous to extreme sports conditions, it is proposed to perform a

head-to-head comparison of these devices before , during and after the Bas van de Goor Foundation *we bike to change diabetes* challenge in September 2018, when a combined team of subjects with diabetes from the Netherlands and Spain will mountainbike in the Sierra Nevada for six days, with a total minimum distance of 263 km and a variable amount of altitude meters (minimal 4753 up to 11000 meters)
(https://bvdgf.org/evenementen/evenement/27041/webike2changediabetes-2018/).

As far as we are aware, the effect of strenuous or extreme exercise on the performance and accuracy of both the ECGM and the FLFM has not been studied extensively outside a clinical setting.

Hypothesis
ECGM will perform better during strenuous to extreme exercise than FLFM

Background
In the past 15 years, continuous glucose monitoring (CGM) systems have become available. These CGM systems measure interstitial fluid glucose levels at rather closely spaced intervals to provide semi-continuous information on glucose levels, allowing identification and signaling 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; most of the available systems need calibrating at least twice daily to allow a sufficiently reliable correlation between interstitial and capillary glucose results. Nevertheless, with the advances in the development of highly accurate and easy to use CGM systems, the ultimate use of an *artificial pancreas* moves closer to become a reality.
Recently, two different variety of a continuous glucose measurement for interstitial glucose fluid monitoring has been introduced in Europe the FreeStyle Libre (Abbott) and the Eversense (Senseonics). FreeStyle Libre is compact, lightweight, has a two-week period of use, and according to the producer does not require calibration by the user (factory-calibrated): the FLFM. Scanning of the sensor by the reader collects the glucose and trend at the moment of scanning plus up to 8 hours of prior readings every 15 minutes. The reader used for FLFM also supports glucose and ketone capillary blood measurements using capillary BG and ketone test strips (Free Style Precision capillary glucose test glucose/ketone strips.).

The Eversense CGM System includes an implantable sensor that lasts up to 90/180 days, a removable smart transmitter, and a mobile app. The system needs calibration twice a day.
The Eversense CGM system measure glucose from interstitial fluid below the skin surface.
The sensor wirelessly sends glucose data to the smart transmitter worn on the upper arm over the sensor insertion site. The smart transmitter calculates the

current glucose values along with the direction it*s headed, how fast, and whether glucose values are expected to exceed pre-set low and high targets. Data and alerts are simultaneously sent to the smartphone app that provides real-time tracking, intuitive displays to help identify patterns, and information to help stay in range.

Independent accuracy assessments of the FLFM are scarce; findings of a study recently performed at our department indicate that the FLFM system in the arm can be used as a workable adjunct in the management of diabetes. However, certain matters definitely need attention while using the CGMs in daily. Effects of deviations can partly be overcome by optimizing the available user instructions.

Study objective

To assess accuracy of ECGM vs FLFM in 25 subjects with diabetes before, during a 6 day mountainbike tour and after the tour in the Sierra Nevada

To assess the (differences in) time in hypo-, normo- ,and hyperglycemia (expressed in minutes per day and episodes per day), using cut-off point as defined by Bolinder et al (ref 8). MAD and MARD in glucose concentrations, using the same incremental glucose concentration steps as in the validation study. Parkes Error grids (ISO15197:2013)

Study design

Prospective, observational study, comparing different methods to assess reliability and accuracy of glucose measurements during strenuous to severe exercise. Specifically: comparison of two devices with capillary measurements.

Data read-out before and during and after the challenge, concentrating on available information from ECGM and FLFM, as well as the capillary blood glucose (automatic stored in FLFM reader(measurements (to be performed as standard 7 times daily, and on indication (hypoglycemic symptoms; hypoglycemia shown on one or both of the devices, also when no hypoglycemia symptoms are present).

Insertion and removal of the ECGM:
Insertion and removal of the sensor will be done by certified doctors. A doctor is certified by Senseonics after three insertions.
Insertion and instruction of using the sensor will be done within 2 months prior to the Sierra Nevada Challenge.

For Spain:
Because the participants are divided over Spain, we will look at 4 suitable hospital locations where the insertion can take place performed by certified

doctors for this action (Pamplona, Madrid, Sevilla/Granada and Oviedo).
For The Netherlands:
Insertion will take place at the Isala Hospital in Zwolle by certified.

Insertion of the FLFL:
Insertion of the FLFL will be done first day at the Sierra Nevada

Study burden and risks

In principle, CGM is a common use in subjects with diabetes performing strenuous to extreme sports / exercise. The extra burden is that one sensor will be placed via a small incision and wearing not one but two devices. No extra risks involved

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

Subjects with type 1 or type 2 diabetes mellitus, using insulin either by MDI or by CSII
Being fit enough to participate in the Bas van de Goor Foundation *we bike to change diabetes* challenge in September 2018. and willing to spend a week in resting conditions in the week after the challenge.
Willing to accept insertion and extraction of ECGM.
Written informed consent

Exclusion criteria

Unable to understand the proposals in Dutch or Spanish
A condition likely to require magnetic resonance imaging for the duration of the study.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-08-2018
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2018

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

ID: 27357
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL66388.075.18
OMON	NL-OMON27357