Performance of the Medtronic Guardian Connect vs the Free Style Libre Flash Monitor in extreme sports conditions in subjects with diabetes

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Primary objective To assess accuracy of GCCGM vs FLFM in 18 subjects with diabetes during a 6 day mountainbike tour in the AlpsSecondary objectives To assess the (differences in) time in hypo-, normo- ,and hyperglycemia (expressed in minutes per…

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

Summary

ID

NL-OMON44483

Source
ToetsingOnline

Brief title
performance of CGMs during strenuous and extreme sports

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: voorziening van materialen

Intervention

Keyword: Blood glucose, Continuous Glucose Registration, Diabetes

Outcome measures

Primary outcome

A: Time in hypoglycemia comparing FLFM and GCCGM.

B: MAD and MARD comparing FLFM, GCCGM and capillary measurements.

Secondary outcome

A: time in normo- and in hyperglycemia, again comparing both devices.

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

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 CGMs is the Guardian Connect CGM (GCCGM), with an improved easiness of use and practical applicability under a large range of circumstances.

Relying on a CGM device implicates the assumption, that the device will be accurate and reliable. Recently, another device registering glucose continuously, has entered the market: the FreeStyle Libre Flash Monitor (FLFM).

For assessment of the accuracy and reliability of both the GCCGM and the FLFM under strenuous to extreme sports conditions, it is proposed to perform a head-to-head comparison of these devices during the Bas van de Goor Foundation *we bike to change diabetes* challenge in September 2017, when a combined team of subjects with diabetes from the Netherlands and Spain will mountainbike in the Mount Blanc massif for six days, with a total minimum distance of 218 km and a variable amount of altitude meters (up to 7848 meters)

(https://bvdgf.org/evenementen/evenement/22613/webike2changediabetes/).

In an earlier validation study, we had to conclude, that the FLFM shows less (albeit still acceptable) accuracy than other glucose measurement techniques. With a standard meal test, glucose levels lagged behind with the FLFM, whereas the results obtained with the Medtronic iPro2 Professional CGM were comparable to those obtained with Statstrip as a *semigolden* standard (traced and aligned to the highest level order of methodology: isotope dilution gas chromatography, mass spectrometry).
Moreover, the FLFM tended to show lower glucose levels than actually present in the lower regions, especially with glucose levels < 4 mmol/l (MARD approx. 20%), and higher than present glucose levels in the higher regions.
Still, user satisfaction was considerable. Despite the lack of alarms or automated registering, the FLFM is much appreciated by many of the users.
As far as we are aware, the effect of strenuous or extreme exercise on the performance and accuracy of both the GCCGM and the FLFM has not been studied extensively outside a clinical setting.

The MARD of 20% of the FLFM elicits concern. Hypoglycemia risk is a major issue during strenuous and extreme exercise. Users of glucose measurement devices need those devices to be as accurate as possible. In our opinion, falsely low glucose levels as shown by the FLFM in earlier research would be a disadvantage for an exercising person with diabetes for a variety of reasons.

Study objective

Primary objective To assess accuracy of GCCGM vs FLFM in 18 subjects with diabetes during a 6 day mountainbike tour in the Alps
Secondary objectives To assess the (differences in) time in hypo-, normo- ,and hyperglycemia (expressed in minutes per day and episodes per day). MAD and MARD in glucose concentrations, using the same incremental glucose concentration steps as in the validation study.

Study design

Prospective observational study with within subjects comparison of three methods for glucose assessment: preformance characteristics of Guardian Connect CGM, Free Style Libre Flash Monitor, and capillary measurements during strenuous to extreme sport / exercise

Daily read-out before and during the challenge, concentrating on available information from GCCGM and FLFM, as well as the capillary blood glucose 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)

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 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

Persons with diabetic being fit enough to participate in the Bas van de Goor Foundation *we bike to change diabetes* challenge in September 2017

Exclusion criteria

Persons without diabetic being fit enough to participate in the Bas van de Goor Foundation *we bike to change diabetes* challenge in September 2017

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):	08-09-2017
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	Guardian Connect system/ Free Style Libre system
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-09-2017
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	NL62519.075.17