Bruikbaarheid van de Eversense versus de Free Style Libre Flash Monitor in (tijdens en na) zware en extreme inspanningsomstandigheden bij personen met diabetes

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27357

Source
NTR

Health condition

Diabetes Mellitus, Glucose monitoring

Sponsors and support

Primary sponsor: Isala, Zwolle
Dr. Van Heesweg 2, 8025 AB Zwolle
Postbus 10400, 8000 GK Zwolle
Source(s) of monetary or material Support: Roche Diabetes Care

Intervention

Outcome measures

Primary outcome

Primary endpoints

A: Parkes Error grids (ISO15197:2013) as described by Parkes.
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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. The aim of this study is to determine the performance (compared to capillary measurements) of two CGMs (flash and continous) during and after strenuous and extreme exercise conditions in subjects with diabetes

Study objective

Bij personen met diabetes is een redelijk tot goede metabole controle om verschillende redenen noodzakelijk. Bij actieve proefpersonen die lichaamsbeweging en sportactiviteiten uitoefenen, zou adequate glucoseregulatie, inclusief preventie van hypo- en hyperglycemieën, goede prestaties mogelijk maken. Dit zal des te meer het geval zijn wanneer de sportactiviteit tot het inspannende en extreme gaat. Bruikbaarheid van de Eversense versus de Free Style Libre Flash Monitor in (vóór en na) zware en extreme inspanningsomstandigheden bij personen met diabetes wordt getest.

Study design

start of study 01-08-2018

Strenuous exercise 14/22 - 09-2018

end of study 30-11-2015

Intervention

Wearing two CGMs (Flash and Continous) to assess reliability and accuracy of glucose measurements. Specifically: comparison of two devices with capillary measurements.

Contacts

Public
internist
Universitair Medisch Centrum Groningen
Hanzeplein 1, 9713 GZ Groningen
Afdeling Interne Geneeskunde
Hoofd Diabetes Kenniscentrum Zwolle
Postbus 10400, 8000 GK
Dokter van Heesweg 2, 8025 AB Zwolle
H.J.G. Bilo
Zwolle
The Netherlands
038-4242518
Scientific
internist
Universitair Medisch Centrum Groningen
Hanzeplein 1, 9713 GZ Groningen
Afdeling Interne Geneeskunde
Hoofd Diabetes Kenniscentrum Zwolle
Postbus 10400, 8000 GK
Dokter van Heesweg 2, 8025 AB Zwolle
H.J.G. Bilo
Zwolle
The Netherlands
038-4242518

Eligibility criteria

Inclusion criteria

25 Participants with DM type 1 and DM type 2 will be recruited by the researcher via the Bas van de Goor foundation. Being fit enough to participate in the Bas van de Goor Foundation “we bike to change diabetes” challenge in September 2018

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 type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-08-2018
Enrollment:	25
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 45979
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7133
NTR-old	NTR7330
CCMO	NL66388.075.18
OMON	NL-OMON45979

Study results