Energy expenditure and (assessment of) glucose regulation of participants with diabetes mellitus during and after the Camino: SENSOR-D-4

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

Summary

ID

NL-OMON48461

Source
ToetsingOnline

Brief title
SENSOR-D-4

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: gelden Stichting onderzoek chronische ziektes in Zwolle

Intervention

Keyword: Continuous Glucose Monitoring, Diabetes, Energy expenditure, Glucose

Outcome measures

Primary outcome

Part 1 - study a: Sensewear use

Some hypotheses with regards to energy expenditure can be formulated:

1. TEE, BEE and AEE are influenced by (the presence of DM and) the degree of chronic glucose control (as measured by HbA1c)

2. TEE, BEE and AEE are influenced by the presence of microvascular complications, especially autonomic neuropathy

3. the deviations will fluctuate in intensity with different degrees of actual blood glucose concentrations (as assessed by the readings of the DG6)

Whether all these points can be addressed in the proposed study, remains to be seen. Since it is proposed to only study people with diabetes, there will be no non-diabetic control group.

study b: DG6 use and buddy function

Supporting users of the DG6 to recognize (early) forewarnings and signs of hypoglycemia by adding a buddy might add to a higher received QoL and safety :

1. use of the buddy function of the DG6 will result in more confidence of users during exercise

2. Use of the buddy function of the DG6 will result in less time in

hypoglycemia on exercise days with the buddy function vs exercise days without the buddy function

study c: assessment of accuracy, reliability and user-friendliness of DG6

Accuracy and reliability of the both devices will be tested, using the same protocol as in earlier studies, with the request to the participants to control their capillary glucose levels at least six times daily.

Secondary outcome

n.a.

Study description

Background summary

People known with diabetes do benefit from regular exercise, especially when this exercise is part of a healthy lifestyle. Despite this fact, starting and maintaining a healthy lifestyle including regular exercise, remains a challenge for a considerable part of the population known with diabetes.
Barriers can be both somatic as psychological. As for the somatic barriers, it is known that in subjects with diabetes, maximum levels of energy expenditure (EE) may be lower during heavy exercise than can be attained by non-diabetic subjects; furthermore, subjects with diabetes apparently do not reach a resting energy expenditure as low as non-diabetic subjects. Those differences are known to be more pronounced when diabetes is less controlled.
Another factor limiting the amount of exercise is actual glucose control, especially the occurrence of hypoglycemia when exercising. Many people with diabetes struggle to find an equilibrium between intensity and duration of exercise, insulin dose, and energy uptake. Continuous or flash glucose monitoring may help to support decision making and diagnosing dysglycemia during exercise, but only to a certain extent. Hypoglycemia signals can be masked by the body reactions to the exercise strains, such as sweating, dizziness, and tachycardia.

The proposed study will include assessment of various measures of energy expenditure (as measured with a Sensewear device) in relation to the degree of metabolic control (specifically during a week of exercise: walking part of the

Camino, and the week thereafter, in order to be able to compare results between a week of comparatively high energy expenditure and a week of normal daily activities).
Furthermore, a new tools for continuous glucose monitoring (CGM), the Dexcom G6 will be used, in order to monitor glucose levels throughout the two weeks, and to assess their accuracy and user friendliness during the two weeks.

Study objective

Within the proposed study design it is possible to answer more study questions within the same population and within the same timeframe without adding much burden to the study participants. measurements and analyses will be performed both during a period of prolonged moderate exercise (walking part of the Camino), and during a week of normal daily activities.

Study a: In the proposed first study, the DG6 will be used as the provider of actual glucose information in relation to the energy expenditure as measured with Sensewear devices.
Study b: In the second study, each user of the DG6 will be allocated to a buddy, which will get the same information and warning signals as the user.
Study c: In the third study, readings of DG6 will be compared

Study design

observational study

Study burden and risks

In principle, CGM is a common use in subjects with diabetes performing exercise. The extra burden is that one extra sensor will be placed. 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 Camino walking challenge September 2019.

Exclusion criteria

Those subjects who participate in the Camino challenge but abstain from participating in the study. Unable to understand the proposals in Dutch or Spanish

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	31-08-2019
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	energy expenditure measurement device; continuou glucose measurement device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	30-07-2019
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	NL70456.075.19