Collection of continuous glucose monitoring and reference glucose values to develop and test algorithms for a smart continuous glucose monitor.

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The aim of this study is the collection of clinical data to develop and test calibration, filtering and prediction algorithms to be embedded in the so-called *smart sensor* for the enhancement of continuous glucose monitoring outcomes. In particular...

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

Summary

ID

NL-OMON34241

Source
ToetsingOnline

Brief title
CGM data for sensor algorithm development.

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: closed-loop, continuous glucose monitoring, diabetes, glucose sensor

Outcome measures

Primary outcome

Main study parameters will include CGM data, Self Measurement of Blood Glucose

(SMBG) data, insulin doses, composition of meals and calibration data.

Secondary outcome

the collected data will be used for the identification of the parameters, i.e.

the gradient and time constant, which characterize the BG-to-IG dynamic model.

Study description

Background summary

In recent years, Continuous Glucose Monitoring (CGM) systems have become available for patients with diabetes. Most CGM sensors measure glucose subcutaneously in the interstitial fluid. This provides the least discomfort for patients and is a suitable method for CGM at home. CGM is an essential part in the development of artificial pancreas systems (AP-systems), in which the CGM data can be used by an algorithm to automatically determine and administer the appropriate amount of insulin needed to establish euglycemia by an insulin pump. Several initiatives are underway to develop these AP-systems. Inaccuracy of CGM hampers the development of these AP-systems however, in part because there is a lag between blood glucose and subcutaneously measured glucose by means of CGM. This lag can cause suboptimal control by the AP-system. Therefore this lag needs to be addressed. One method of addressing this lag is by adjusting the algorithm within CGM*s to take this lag into consideration. To improve this algorithm data is needed comparing CGM data to blood glucose data. During this trial we will collect this data using one of the leading CGM brands of sensors: The Seven Plus sensor. The DexCom Seven Plus sensor exploits the glucose-oxidase principle, and measures an electrical current which is related to the interstitial glucose (IG) concentration. The current is transformed into a glucose concentration using a calibration procedure that exploits one or more blood glucose (BG) references. The current

and the BG references are collected in different sites and the existence of a dynamic system between them is proved. If the dynamic system is not taken into account, the output of the sensor could lack in accuracy.

Study objective

The aim of this study is the collection of clinical data to develop and test calibration, filtering and prediction algorithms to be embedded in the so-called *smart sensor* for the enhancement of continuous glucose monitoring outcomes. In particular, the collected data will be used for the identification of the parameters, i.e. the gradient and time constant, which characterize the BG-to-IG dynamic model.

Study design

The study is an open-label study. The study will include a total of 12 patients (3 in each of the four participating clinical centers of the consortium). Drop-outs will be replaced. The study will take 7 days. On 6 days the patient will wear the CGM in his/her own surroundings (e.g. at home), on 1 day the patient will be admitted to the clinical research unit.

Study burden and risks

Patients will visit the CRC on day 1 and 7 for insertion and removal of the CGM sensor, estimated duration of these visits will be 2 hours and 30 minutes respectively. Patients will be admitted to the clinical research ward on day 3, 4 or 5 for a duration of 26 hours. Blood samples will be drawn during the night and after dinner. Risk to the patient includes haematoma or infection around the blood collection catheter sites or the CGM insertion site.

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

aged 18 years or above
diagnosed with Type 1 Diabetes Mellitus at least 6 months according to the WHO definition
Body Mass Index (BMI) <35 kg/m²
willing to wear a continuous glucose monitoring (CGM) device for the duration of the seven study days and undergo all study procedures
HbA1c <10%

Exclusion criteria

Patient is pregnant, or breast feeding during the period of the study.
Patient is using a medication that significantly impacts glucose metabolism
Patient has severe medical or psychological condition(s) or chronic conditions/infections that in the opinion of the Investigator would compromise the patient*s safety or successful participation in the study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2010
Enrollment:	3
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL33165.018.10