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Collection of and monitoring continuous glucose data to test algorithms for a glucose monitor (DATA Trial)

Submission date
30/09/2011

Recruitment status
No longer recruiting

Registration date
25/10/2011

Overall study status
Completed

Last Edited
27/11/2012

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Insulin is given to treat diabetes mellitus type 1. To know how much insulin needs to be given, patients need to be aware of their glucose levels so that they do not over or underdose their insulin. The information about glucose levels is traditionally acquired by fingerprick. Recently, devices have been made which measure glucose continuously by inserting a small needle-like sensor in the fat of the skin. These continuous glucose monitors (CGM) are an important tool in the treatment of diabetes and in the development of an artificial pancreas. An artificial pancreas is a device which automatically makes decisions about what amount of insulin is needed based on the glucose data from the sensor; the artificial pancreas then delivers this insulin automatically. This trial will collect data from two glucose sensors used in the treatment of patients with diabetes.

Who can participate?
Patients with type 1 diabetes for at least 6 months, aged 18 years or above, with a Body Mass Index (BMI) of less than 35 kg/m^2. Participants had to be willing to wear a CGM device for the duration of the seven study days and undergo all study procedures.

What does the study involve?
The two sensors were inserted under the skin and recording was started. Sensor data was collected over a seven day period while the participants were at home, and at the clinical research centre. All participants were treated the same way.

What are the possible benefits and risks of participating?
There are no known benefits to participants of taking part in this study. There is a small risk of infection at blood collection sites and infection or irritation at the sensor site.

Where is the study run from?
Academic Medical Centre, The Netherlands

Profil GmbH, Neuss, Germany
Medical University Graz, Austria
(Medical University and Hospital of Padua, Padua, Italy

When is the study starting and how long is it expected to run for?
The study started in December 2010 and ended in February 2011

Who is funding the study?
European Community Framework Programme 7 ref: FP7-ICT-2009-4

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
WP1.1/01

Study information

Scientific Title
Collection of continuous glucose monitoring and reference glucose values to develop and test algorithms for a continuous glucose monitor

Acronym
DATA

Study objectives
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 g and time constant τ, which characterize the BG-to-IG dynamic model.

Ethics approval required

Old ethics approval format

Ethics approval(s)
1. Medical Ethics Review Academic Medical Center Amsterdam [Medisch Ethische Toetsingscommissie Academisch Medisch Centrum Amsterdam], 26 August 2010, ref: 10/195
2. Ethics Committee of the Medical University of Graz [Ethikkommission der Medizinischen Universität Graz]
3. Hospital and University of Padua Ethics Committee for Experimentation [Azienda Ospedaliera e Università degli Studi di Padova Comitato Etico per la Sperimentazione]
4. Ethics Committee of the Medical Association of North [Ethikkommission der Ärztekammer Nordrhein]

Primary study design
Observational

Study design
Open-label non-randomised controlled trial

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Diabetes mellitus type 1

Interventions
2 CGM DexCom Seven Plus (Sensor 1 and Sensor 2) will be inserted on the participant and recording will start. In both sensors, standard calibration will be performed right after the insertion. Sensor data will then be collected over the course of a seven day period all of which are in an outpatient setting, with the exception of day 3, 4 or 5 where CGM data will be collected in the clinical research center after meal challenges.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Continuous Glucose Monitoring (CGM) data
2. Self-monitoring blood glucose (SMBG) data
3. Insulin doses
4. Composition of meals and calibration data

Key secondary outcome(s)
The collected data will be used for the identification of the parameters, i.e. the gradient g and time constant τ, which characterize the BG-to-IG dynamic model

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Diagnosed with Type 1 diabetes mellitus at least 6 months according to the WHO definition
3. Body Mass Index (BMI) <35 kg/m²
4. Willing to wear a Continuous Glucose Monitoring (CGM) device for the duration of the seven study days and undergo all study procedures
5. HbA1c <10%
6. If patient is on antihypertensive, thyroid, anti-depressant or lipid lowering medication, patient must have stability on the medication for at least 1 month prior to enrolment in the study and for the study duration
7. Signed informed consent form prior to study entry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patient is pregnant, or breast feeding during the period of the study
2. Patient is using a medication that significantly impacts glucose metabolism (oral steroids) except if stable for at least the last three months and expected to remain stable for the study duration
3. Has severe medical or psychological condition(s) or chronic conditions/infections that in the opinion of the Investigator would compromise the patients safety or successful participation in the study
4. Patient is actively enrolled in another clinical trial or took part in a study within 30 days
5. Known adrenal gland problem, pancreatic tumour, or insulinoma
6. Retinopathy except background retinopathy according to eye fundus examination during the last year
7. Known bleeding diathesis or dyscrasia
8. Inability of the patient to comply with all study procedures
9. Inability of the patient to understand the patient information
10. Patient donated blood in the last 3 months

Date of first enrolment
01/12/2010

Date of final enrolment

01/03/2011

Locations

Countries of recruitment
Austria

Germany

Italy

Netherlands

Study participating centre
PO Box 22660
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Sponsor information

Organisation
Academic Medical Centre (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Government

Funder Name
European Community Framework Programme 7 ref: FP7-ICT-2009-4

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration