Algorithm to control Postprandial, Post exercise and night glucose Excursions in a portable closed Loop format, APPEL 4

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

Summary

ID

NL-OMON40156

Source
ToetsingOnline

Brief title
APPEL 4

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
Diabetes Mellitus type 1 / diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Europese Unie

Intervention

Keyword: artificial pancreas, bihormonal closed loop, diabetes type 1

Outcome measures

Primary outcome

Main study parameter is the mean sensor glucose concentration, which will be compared between open and closed loop.

Secondary outcome

Secondary parameters are:

-the proportion of time spent and the number of events in the following categories: low glucose, very low glucose, dangerously low glucose, high glucose, very high glucose, and dangerously high glucose;

-the number of carbohydrate-treated hypoglycemic events;

-the proportion of time spent in euglycemia;

-glycemic variability;

-day, night, and postprandial mean glucose concentration;

-MARD (mean absolute relative difference) of the glucose sensors compared to self-monitored blood glucose;

-Heart rate and physical activity;

-Mean glucose concentration per day (closed loop only);

-Time that the control algorithm is inactive (closed loop only).

Study description

Background summary

In previous studies, we tested the feasibility of a bi-hormonal reactive closed loop system without mealtime announcement. This system for automated control of blood glucose in patients with type 1 diabetes was tested in the clinical research center (APPEL 1 and 2) as well as at the home of the patients, for 48 hours (APPEL 3). Glucose control with automated closed loop control was comparable to patient-managed open loop control. The closed loop system has been further developed and miniaturized (from backpack to smartphone size) in order to interfere as little as possible with daily patient life.

Study objective

The main objective is to assess the efficacy of the closed loop system at the home of the patient. Secondary objectives are to assess the safety of the new prototype while the telemonitoring intensity is being reduced during the trial; to investigate the use of the accelerometer incorporated in the device; to explore whether the closed loop control improves over time; and to assess the glucose measurement performance of the new prototype.

Study design

The study is a multicenter randomized cross-over trial.

Intervention

The intervention is four days of closed loop control of blood glucose with the miniaturized prototype. The prototype uses two subcutaneous glucose sensors, two subcutaneous infusion sets, and incorporates two pumps and a patented reactive closed loop algorithm. The patients will also wear a heart rate belt. On the first morning, the patients receive training before the closed loop system is started and they will stay one night at the clinical research center. During the first twelve hours at home the patients are continuously monitored with a wireless telemedicine system. Subsequently, the monitoring intensity will be reduced, from every four hours at first to eventually once every twelve hours. The control arm (open loop) consists of patient-managed CSII therapy and blinded continuous glucose monitoring at home for four days.

Study burden and risks

The patients will have to wear the prototype with the subcutaneous sensors, infusion sets and heart rate belt. Furthermore, they will be asked to keep a diary with self-monitored blood glucose, meals and activities. During the first day of closed loop control the patients will be admitted to the clinical research center. There are no major risks associated with this study. Potential risk is the administration of the incorrect amount of insulin or glucagon, which may result in hypo- or hyperglycemia. This may be caused by failure of the closed loop algorithm, technical failure of the system, or incorrect sensor

glucose measurements. With multiple risk control measures the risk for the patients is minimized. The system contains a controller and a separate back up processor and several alerts are built in the system. The patients are monitored visually via wireless connection, both in the clinical research center and at home. During the first day the research team, which contains at least a medical doctor or research nurse and an engineer, is present. The individual benefit for the participating patients is a potentially very well regulated glucose during the test. The potential benefit from this pilot study is however more in general; the further development of a portable closed-loop system for automated glucose control.

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

Diagnosed with diabetes mellitus type 1;
Treated with continuous subcutaneous insulin infusion for a minimum of 6 months;
Age between 18 and 75 years.

Exclusion criteria

Impaired awareness of hypoglycaemia according to Gold and/or Clarke questionnaire ;
BMI > 35 kg/m2;
HbA1c > 11.0%.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-06-2014
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Artificial pancreas for closed loop control of blood glucose
Registration:	No

Ethics review

Approved WMO Date:	04-09-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-04-2014
Application type:	Amendment
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	NL43469.018.13