Algorithm to control Postprandial, Post exercise and night glucose Excursions in a portable closed Loop format, APPEL 5

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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-OMON46864

Source
ToetsingOnline

Brief title
APPEL 5

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 percentage of time spent in the target range

(3.9-10 mmol/l), which will be compared between open and closed loop.

Secondary outcome

Secondary parameters are:

-The proportion of time spent in hypoglycemia and hyperglycemia;

-The number of carbohydrate-treated hypoglycemic events;

-Mean or median glucose concentration;

-Glycemic variability;

-Day, night, and postprandial mean or median sensor glucose concentration;

-Day and night time spent in hypo-, hyper- and euglycemia;

-Quality of life and treatment satisfaction scores;

-Percentage of time that the closed loop algorithm is active;

-Mean absolute relative difference for the glucose sensor of the closed loop

system.

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). After the APPEL 3 study the closed loop system was miniaturized to near smartphone format and this system was tested for 3 days at home (APPEL 4). The results of the APPEL 4 study suggest comparable median glucose levels for automated closed loop control and patient-managed open loop control, but improved time in target (3.9-10 mmol/l) with closed loop control. After APPEL 4 some improvements have been made to the miniaturized prototype to allow patients to operate the system independently.

Study objective

The main objective of this study is to assess the efficacy of the closed loop system over an extended period. Secondary objectives are to assess the safety of the closed loop system; to determine the time that the control algorithm is active; to determine the glucose measurement performance; and to assess quality of life and the treatment satisfaction for the closed loop system.

Study design

The study is a multicenter randomized cross-over trial, preceded by a limited number of feasibility tests during which the prototype improvements are assessed.

Intervention

The intervention is two weeks 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. During 4-6 days before the intervention the patients receive training on the use of the closed loop system and will start using the system under close supervision. The control arm (open loop) consists of the patient*s standard therapy (SAP or CSII) at home. The feasibility patients will only perform the closed loop part.

Study burden and risks

The patients will have to wear the prototype with the subcutaneous sensors and infusion sets. Furthermore, they will be asked to keep a diary with self-monitored blood glucose, meals and activities. 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 safety processor and several alerts are built in the system. The patients can be monitored via wireless connection. The tele monitoring system alerts the research team in case of poor glucose

control, technical failure or unreliable sensor glucose measurements. The individual benefit for the participating patients is a potentially very well regulated glucose during the test. The potential benefit from this 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 sensor augmented pump therapy or insulin pump for a minimum of 6 months;
Age between 18 and 75 years.

Exclusion criteria

Impaired awareness of hypoglycemia;
BMI > 35 kg/m2;
HbA1c > 97 mmol/mol.

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):	10-03-2019
Enrollment:	34
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	14-12-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	20-12-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2019
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	NL55693.018.15