Algorithm to control Postprandial, Post exercise and night glucose Excursions in a portable Closed Loop format in patients after Total Pancreatectomy, APPEL 5+

Published: 11-03-2020
Last updated: 10-04-2024

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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-OMON49195

Source
ToetsingOnline

Brief title
APPEL 5+

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: Ministerie van OC&W,Inreda Diabetic BV

Intervention

Keyword: Artificial Pancreas, Bihormonal closed loop, Total pancreatectomy

Outcome measures

Primary outcome

The 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

The secondary study parameters are:

- The proportion of time spent in hypoglycemia and hyperglycemia;

- Median glucose concentration;

- Glycemic variability;

- Day and night median glucose concentration;

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

- 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 diabetes was tested in clnical research center (APPEL 1 and 2) as well as at the home of the patients (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. In the APPEL 5 study the updated system was used by patient with type 1 diabetes at home during two weeks. The system was effective and safe. In patients after total pancreatectomy glucose control is often difficult due to removal of the alpha and beta cells. Probably, the artificial pancreas will improve glucose control in these patients.

Study objective

The main objective of this study is to assess efficacy of the closed loop system in patients after total pancreatectomy. Secondary objectives are to assess the safety of the closed loop system; to determine the time that the control algorithm is active; and to determine the glucose measurement performance.

Study design

This is randomized cross-over trial, preceded by two patients undergoing feasibility tests.

Intervention

The intervention is one week closed loop control of blood glucose with the miniaturized prototype after a training period of 4-6 days. 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 feasibility patients will only perform the training period.

Study burden and risks

The patients will have to wear the prototype with the subcutaneous sensors and infusion sets. Furthermore, during the training period 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 a wireless connection. The telemonitoring 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.

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

Patients who underwent total pancreatectomy;
Age *18 years.

Exclusion criteria

Impaired awareness of hypoglycemia;
Total pancreatectomy performed within less than 3 months before start of trial;
BMI > 35 kg/m2;
HbA1c > 90 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):	21-08-2020
Enrollment:	12
Type:	Actual

Medical products/devices used

Generic name:	Artificial pancreas for closed loop control of blood glucose
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-03-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-08-2020
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
ClinicalTrials.gov	NCTnummervolgt
CCMO	NL72029.018.19