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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20928

Source
NTR

Brief title
APPEL5+

Health condition

Total pancreatectomy after any indication

Sponsors and support

Primary sponsor: Amsterdam UMC (Academic Medical Center)
Source(s) of monetary or material Support: Amsterdam Gastroenterology Endocrinology Metabolism

Intervention

Outcome measures

Primary outcome

The proportion of time spent in the target range (3.9-10 mmol/l), calculated the closed loop period (without the training period).

Secondary outcome

The safety parameters are:
The proportion of time spent in the following categories:
• Hypoglycemia (<3.9 mmol/l);
• Hypoglycemia (<3.3 mmol/l);
• Hyperglycemia (>10 mmol/l);
• Hyperglycemia (>13.9 mmol/l).

Secondary performance parameters are:
• Median sensor glucose concentration;
• Glycemic variability;
• Day and night median sensor glucose concentration;
• Day and night time spent in hypo-, hyper- and euglycemia.

The day period is defined as the time between 6 AM and 12 PM, and the night period is defined as the time between 12 PM and 6 AM.

Other secondary outcomes:
• Percentage of time that the closed loop algorithm is active (closed loop period only).
• Glucose measurement performance: absolute relative difference (ARD) for the paired SMBG-glucose sensor reading in the closed and open loop period. Only the 7-point glucose profile SMBGs will be used for this assessment. The mean (MARD) will be calculated with a MARD reliability index to assess the certainty of the MARD values. To compare the glucose sensors in the closed loop period the Precision Absolute Relative Difference (PARD) will be calculated.

Study description

Background summary

Glucose control in patients with diabetes type 3c (DM3c) after total pancreatectomy is difficult due to absence of both alpha and beta cells. In a recent study, a bihormonal reactive closed loop system (artificial pancreas) was tested for glucose control in patients with type 1 DM and showed better glucose control compared to standard open loop therapy. This closed loop system might also result in improved glucose control in patients with DM3c.

The main objective of this study is to assess the efficacy of the closed loop system over an extended period in patients with DM3c 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; to determine the glucose measurement performance.

This pilot study is a randomized, monocenter cross-over study, preceded by a feasibility test in two patients. The study population will comprise 12 patients with DM3c after total pancreatectomy.

The intervention is one week closed loop control of blood glucose with the artificial pancreas. The artificial pancreas 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), also one week, consists of the patient's standard therapy at home. The feasibility patients will only perform the training.

The main study parameter is the percentage of time spent in the target range (3.9-10mmol/l), which will be compared between open and closed loop. The individual benefit for the participating patients is a potentially very well regulated blood glucose during the test.

Study objective

Better glucose control during the closed loop system compared to standard open loop therapy

Study design

Primary outcome
The proportion of time spent in the target glucose range will be compared between open and closed loop. In the open loop period, the glucose level will be measured by continuous glucose monitoring. Patients will receive a blinded continuous glucose monitoring(Dexcom) which should be calibrated daily by the patients and can be performed without unblinding. During the closed loop, the glucose levels are measured by the glucose sensors of the artificial pancreas.

Secondary outcome
The secondary safety and performance parameters will also be compared between the open and closed loop. Glucose measurement in the open and closed loop is measured by a continuous glucose monitoring system or the artificial pancreas, respectively.
The percentage of the day that the closed loop algorithm is active is stored by the artificial pancreas and could be uploaded.

Intervention

Artificial pancreas

Contacts

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Eligibility criteria

Inclusion criteria

• Patients who underwent total pancreatectomy;
• Diabetes treatment with continuous subcutaneous insulin infusion, sensor augmented pump therapy or subcutaneous insulin injections;
• Age ≥18 years.

Exclusion criteria

• Total pancreatectomy was performed within less than 3 months before start of the trial;
• Impaired awareness of hypoglycemia (score ≥ 4) according to Gold and/or Clarke questionnaire;11,12
• BMI > 35 kg/m2;
• HbA1c > 90 mmol/mol;
• Use of oral corticosteroids;
• Use of acetaminophen during the open loop or closed loop period, as this may influence the sensor glucose measurements;
• Limited ability to see, and to hear or feel alarm signals of the closed loop system;
• Refusal of disconnecting own glucose sensors during the closed loop system study period;
• Pregnancy and/or breastfeeding;
• Living alone during the night during the closed loop period (the patient may ask someone to stay over temporarily);
• Any condition that the local investigator feels would interfere with study participation or the evaluation of the results.
• Patients who are not motivated or not willing to comply with the artificial pancreas therapy;
• Patients undergoing treatment with Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, X-ray or high frequency electrical heat (diathermy) treatment while

wearing the AP system (must be removed);
• Patients using the artificial pancreas system during sauna or swimming;
• Known or suspected allergies or problems related to subcutaneous administration of insulin or glucagon;
• Artificial pancreas therapy is not recommended for people who are unwilling or unable to maintain contact with their medical professional;
• Alcohol and drug abusing patients;
• Patients with insufficient general mental and physical abilities;
• Known or suspected problems related to enzyme based glucose sensor usage;
• Patients receiving dialysis.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-09-2020
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	01-09-2020
Application type:	First submission

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
NTR-new	NL8871
Other	METC AMC : 2019_277#B2020455

Study results