Efficacy of a bihormonal closed loop system.

No registrations found.

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

Summary

ID

NL-OMON20851

Source
Nationaal Trial Register

Brief title
APPEL

Health condition

diabetes type 1
Artificial pancreas
closed loop
glucagon

kunstalvleesklier

Sponsors and support

Primary sponsor: AMC Amsterdam
Source(s) of monetary or material Support: AMC

Intervention

Outcome measures

Primary outcome

1. Difference in postprandial and post exercise venous glucose excursions measured as area under the curve comparing closed loop format to usual care;

2. Difference in postprandial and post exercise sensor glucose excursions measured as area under the curve comparing closed loop format to usual care.

Secondary outcome

1. Difference in the proportion of time spent in euglycaemia (glucose 4.0 – 7.0 mmol/l) comparing the closed loop format to usual care;

2. Difference in numbers of hypoglycaemias (glucose at or below 3.9 mmol/l) comparing the closed loop format to usual care.

Study description

Background summary

Rationale:

Over the last decade insulin delivery and blood glucose monitoring have evolved facilitating better glucose control. Continuous Subcutaneous Insulin Infusion (CSII) and Continuous Glucose Monitoring (CGM) sensors combined with an insulin delivery algorithm results in a closed loop system: An artificial pancreas. The “Algorithm to treat postprandial glycaemic excursions using a closed loop format, APPEL pilot study” (MEC 08/341) demonstrated that the Robopump provided comparable postprandial glycaemic control as usual care. In the meantime, the glucose sensor has been replaced to increase technical reliability and patient comfort, and the algorithm underwent minor revisions. The aim of this pilot study is to test the efficacy of the improved closed loop system in a clinical research unit, not only following food intake, but also after exercise.

Objective:

Main objective:

To investigate postprandial and post-exercise glucose excursions comparing closed loop system to usual care.

Secondary objective:

1. To investigate time spent in euglycaemia comparing closed loop system to usual care;

2. To investigate the number of hypoglycaemias comparing closed loop system to usual care;

3. To investigate the reaction of heart rate on glucose excursions.

Study design:

The study is a single centre interventional invasive pilot study.

Study population:

The inclusion criteria are patients with diabetes type 1 treated with continuous subcutaneous insulin infusion (CSII or insulin pump), aged from 18 to 75 years with a BMI below 35 kg/m2.

Intervention:

All participants will wear a subcutaneous glucose sensor, an insulin pomp and a glucagon pump, all connected to a computer that contains a patented proportional derivative glucose control algorithm. This closed loop format will control the glucose excursions during breakfast, exercise and lunch.

Main study parameters/endpoints:

During the study the following parameters will be measured:

1. Glucose concentration;

2. Heart rate.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All participants will undergo a vena puncture to insert an infusion system to collect blood samples during the day. Blood samples are taken after meals and after exercise every 30 minutes and every 10 minutes during the exercise. In total 90 ml blood is taken to measure the glucose concentration.

Study objective

Glucose control by closed loop in diabetes type 1 is equal to glucose control by insulin pump.

Study design

Start 1-1-2011.

Intervention

Open loop (insulin pump treatment) is compared to closed loop.

10 patients attend the CRC. In open loop, the patients will be responsible for the glucose control during postprandial breakfast, post exercise and postprandial lunch period.

In closed loop, an algorithm is responsible for glucose control during the day.

Patients will wear glucose sensor and venous blood samples are taken for glucose measurements.

Contacts

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Eligibility criteria

Inclusion criteria

1. Diabetes mellitus type 1 treated with CSII for a minimum of 6 months;

2. Age: 18-75;

3. Willing and able to sign informed consent.

Exclusion criteria

1. BMI > 35 kg/m2;

2. HbA1c > 11.0%;

3. Use of heparin, coumarin derivatives or oral corticosteroids;

4. Skin condition prohibiting needle insertion;

5. Pregnancy and/or breastfeeding;

6. Any condition that the local investigator feels would interfere with trial participation or the evaluation of results.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	10

Type: Anticipated

Ethics review

Positive opinion
Date: 14-07-2011

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	NL2852
NTR-old	NTR2994
Other	METC AMC : 09/263
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
Postprandial glycaemic excursions with the use of a closed-loop platform in diabetes type 1, a pilot study.