Efficacy of a bihormonal closed loop system.

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20851

Bron
Nationaal Trial Register

Verkorte titel
APPEL

Aandoening

diabetes type 1
Artificial pancreas
closed loop
glucagon

kunstalvleesklier

Ondersteuning

Primaire sponsor: AMC Amsterdam
Overige ondersteuning: AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Start 1-1-2011.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-07-2011

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2852
NTR-old	NTR2994
Ander register	METC AMC : 09/263
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

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