Comparison of two artificial pancreas systems for closed-loop blood glucose control versus open loop control in patients with Type 1 diabetes

Published: 17-09-2010
Last updated: 30-04-2024

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Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Interventional

Summary

ID

NL-OMON34528

Source
ToetsingOnline

Brief title
CAT trial

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: Europese Unie

Intervention

Keyword: artificial pancreas, closed loop, diabetes

Outcome measures

Primary outcome

Time spent in target range; this is defined as plasma glucose values between 3.9 and 8.0 mmol/L in the basal or late postprandial state (more than 3 hours after breakfast, lunch and dinner) and plasma glucose values between 3.9 and 10.0 mmol/L in the early postprandial state (first 3 hours after breakfast, lunch and dinner).

Secondary outcome

* Time spent in hypoglycaemia defined as plasma glucose value <3.9 mmol/l

* Time spent in hyperglycaemia, defined as plasma glucose value >8 mmol/l in the basal or late postprandial state and >10 mmol/l in the early postprandial state

* Mean and standard deviation of plasma glucose

* Time spent in target range defined as CGM glucose values between 3.9 and 8.0 mmol/L in the basal or late postprandial state and CGM glucose values between 3.9 and 10.0 mmol/L in the early postprandial state

* Time spent in hypoglycaemia defined as CGM glucose value <3.9 mmol/l

* Time spent in hyperglycaemia, defined as CGM glucose value >8 mmol/l in the basal or late postprandial state and >10 mmol/l in the early postprandial state

* Mean and standard deviation of CGM glucose values

* Total number of insulin units infused

* Median plasma insulin concentration

* Total duration of treatment in minutes

Study description

Background summary

Patients with type 1 diabetes must use the optimal amount of insulin to prevent excessive swings in blood glucose. This requires the patient to be vigilant about their own glucose levels at all times. Finger pricks must be done to determine blood glucose and the patient should determine the appropriate amount of insulin administration in relation to this glucose level and expected food intake and physical activity. This can be tricky, and scientists have been looking for a way to automate the measurement of blood glucose and the administration of insulin. The device that does this is known as the artificial pancreas. The artificial pancreas consists of a subcutaneous continous glucose sensor which measures blood glucose, an insulin pump which provides insulin and a computer algorithm which receives the glucose measurements and controls the pump to administer appropriate amounts of insulin without the need of patient intervention.

Study objective

Objective of the study is the comparison of two previously developed computeralgorithms for the artificial pancreas (closed loop). One algorithm developed by a researchgroup in Cambridge UK, and an algorithm developed by research groups in Padua and Pavia, Italy.
The algorithms will be compared to open loop control (the use of continuous subcutaneous insulin therapy / insulin pump). Performance of the algorithms in terms of keeping the patient in the euglycaemic range will be assessed, also after the meal and following exercise.

Study design

Patients will be admitted to the clinical research ward 3 times, during which they will randomly be assigned to undergo all treatment arms of the study in a cross-over design.

Intervention

The intervention consists of the regulation of plasma glucose by means of the artificial pancreas. The three treatment arms are: 1. closed loop with the algorithm from Cambridge 2. closed loop with the algorithm from padua-pavia 3.

open loop control with CSII/insulin pump.

Study burden and risks

In total there are 7 visits which require patients to come to the hospital, they are listed here:
1. Inclusion visit (1 hour)
2. pre-admission visit for placement of glucose sensor (20 minutes)
3. admission 1 (24 hours)
4. pre-admission visit for placement of glucose sensor (20 minutes)
5. admission 2 (24 hours)
6. pre-admission visit for placement of glucose sensor (20 minutes)
7. admission 3 (24 hours)

This research may involve the following side effects:
- Bruising by placement of the intravenous catheter, the subcutaneous glucose sensor or the insulin catheter.
- Inflammation or skin irritation at the insertion site of the intravenous catheter, the subcutaneous glucose sensor or the insulin catheter.
- hypoglycaemia
- hyperglycaemia
Hypo- or hyperglycaemia during the investigation exceeding pre-determined safety limits will be corrected by the investigator.

Contacts

Public
Academisch Medisch Centrum

Postbus 22660
1100DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Postbus 22660
1100DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

aged 18 years or above
diagnosed with Type 1 diabetes mellitus at least 6 months according to the WHO definition
Body Mass Index (BMI) <35 kg/m²
treated by basal-bolus insulin therapy using an external insulin pump for at least 3 months
willing to use insulin aspart and wear a continuous glucose monitoring (CGM) device for the duration of the three study days and undergo all study procedures

Exclusion criteria

Patient is pregnant, or breast feeding during the period of the study
Symptomatic coronary artery disease
Patient is using a medication that significantly impacts glucose metabolism

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	8
Type:	Anticipated

Medical products/devices used

Generic name:	artificial pancreas
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO
Application type:	First submission
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	NL32634.018.10