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Comparison of two artificial pancreas systems for closed loop blood glucose control versus open loop control in patients with type1 diabetes

Submission date
28/02/2011

Recruitment status
No longer recruiting

Registration date
17/03/2011

Overall study status
Completed

Last Edited
22/11/2013

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
WP3.1/01

Study information

Scientific Title

Comparison of two artificial pancreas systems for closed loop blood glucose control versus open loop control in patients with type 1 diabetes: a randomised, non-blinded, multi-centre, cross-over intervention trial

Acronym
CAT Trial

Study objectives
To compare blood glucose control achieved by two closed loop algorithms to open loop control during night time and daytime.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Medical Ethics Review Academic Medical Center Amsterdam (Medisch Ethische Toetsingscommissie Academisch Medisch Centrum Amsterdam), approved on 13th July 2010, reference number 10/134
2. West Midlands Research Ethics Committee, approved on 25th August 2010, reference number 10/H1208/55
3. Ethics Committee of the Medical University of Graz(Ethikkommission der Medizinischen Universität Graz), approved on 12th October 2010, reference number 21-426 ex09/10
4. Committee to Protect People southern Mediterranean IV (Comité de Protection des Personnes Sud Méditerranée IV), approved on 8th July 2010, reference number 10 06 02
5. Hospital and University of Padua Ethics Committee for Experimentation (Azienda Ospedaliera e Università degli Studi di Padova Comitato Etico per la Sperimentazione), approved on 13th September 2010, reference number 2161P
6. Ethics Committee of the Medical Association of North (Ethikkommission der Ärztekammer Nordrhein), approved on 6th September 2010, reference number 12946

Study design
Randomised non-blinded multi-centre cross-over intervention trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Type 1 diabetes

Interventions
Patients will receive automated closed loop control of their blood glucose for 24 hours, using the Cambridge algorithm on one study day and the IAP algorithm on another study day and also 24 hours of open loop control (conventional usage of CSII) on a control day, in a randomised sequence.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
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)

Key secondary outcome(s))
1. Time spent in hypoglycaemia defined as plasma glucose value < 3.9 mmol/l
2. 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
3. Mean and standard deviation of plasma glucose
4. 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
5. Time spent in hypoglycaemia defined as CGM glucose value < 3.9 mmol/l
6. 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
7. Mean and standard deviation of CGM glucose values
8. Mean absolute difference between plasma glucose values and CGM glucose values
9. Total number of insulin units infused
10. Median plasma insulin concentration
11. Total duration of treatment in minutes

In addition, plasma insulin and glucose concentrations will be used for further modelling studies.

Completion date
01/10/2011

Eligibility

Key inclusion criteria
1. Aged 18 years or above
2. Diagnosed with type 1 diabetes mellitus (DM) at least 6 months according to the World Health Organisation (WHO) definition
3. Body Mass Index (BMI) < 35 kg/m²
4. Treated by basal-bolus insulin therapy using an external insulin pump for at least 3 months
5. 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
6. Trained in carbohydrate counting
7. HbA1c < 10%
8. If patient is on antihypertensive, thyroid, anti-depressant or lipid lowering medication, patient must have stability on the medication for at least 1 month prior to enrollment in the study and for the study duration
9. Signed informed consent form prior to study entry

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patient is pregnant or breast feeding during the period of the study
2. Haematocrit is below 36% (females) and below 38% (males)
3. Symptomatic coronary artery disease (e.g. history of myocardial infarction, history of acute coronary syndrome, history of therapeutic coronary intervention, history of coronary bypass or stenting procedure, stable or unstable angina, positive stress test or catheterisation with coronary blockages > 50%) or congestive heart failure or a history of a cerebrovascular event
4. Patient is using a medication that significantly impacts glucose metabolism (oral steroids) except if stable for at least the last three months and expected to remain stable for the study duration
5. Uncontrolled hypertension with resting blood pressure over 140/90 mmHg
6. Patient is actively enrolled in another clinical trial or took part in a study within 30 days
7. Allergy or adverse reaction to aspart insulin
8. Known adrenal gland problem, pancreatic tumour or insulinoma
9. Current alcohol abuse, substance abuse or severe mental illness, as judged by the investigator
10. Retinopathy except background retinopathy according to eye fundus examination during the last year
11. Known bleeding diathesis or dyscrasia
12. Renal insufficiency with serum creatinine > 150 µmol/L
13. Patient donated blood in the last 3 months

Date of first enrolment
09/03/2011

Date of final enrolment
01/10/2011

Locations

Countries of recruitment
United Kingdom

Austria

France

Germany

Italy

Netherlands

Study participating centre
POBox 22660, room F4-281
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Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Government

Funder Name
European Union (FP7-ICT-2009-4, grant agreement number 247138)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes