

Prevention of nocturnal hypoglycaemia with closed-loop insulin delivery in children and adolescents with type 1 diabetes (T1D)

Submission date

03/06/2009

Recruitment status

No longer recruiting

Registration date

02/07/2009

Overall study status

Completed

Last Edited

27/04/2011

Condition category

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ 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

REC Ref. 06/Q0108/350

Study information

Scientific Title

Three randomised studies to assess closed-loop overnight glucose control as compared to standard pump therapy, copying with variable evening intake and afternoon exercise in youngsters with type 1 diabetes (T1D)

Acronym

APCam (Artificial Pancreas project at Cambridge)

Study objectives

Closed loop systems can reduce risk of nocturnal hypoglycaemia in children and adolescents with type 1 diabetes (T1D) even after variable evening meal intake and differing exercise patterns.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Cambridge Local Ethics Committee approved on the 8th December 2006 (ref: 06/Q0108/350). The last substantive approval was granted on the 20th December 2007.

Primary study design

Interventional

Study design

Phase II randomised controlled interventional crossover group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 1 diabetes

Interventions

The three studies will take place as follows:

1. Comparison of closed loop system with standard CSII (APCam01):

In random fashion, twelve subjects aged 5 to 18 years were treated by overnight closed-loop or CSII on two separate occasions at the Clinical Research Facility 1 to 3 weeks apart. On both study occasions, the subjects consumed a self-selected meal (87 +/- 23g carbohydrates) at 18:00 accompanied by prandial insulin (9 +/- 5U) calculated according to subject's insulin-to-carbohydrate ratio. The meals were identical on both study nights. Closed-loop control was applied between 20:00 and 08:00 the next day. On the CSII night, the subject's standard insulin pump settings were applied.

2. Evaluation of the effects of a variable-content large evening meal (APCam02):

Six subjects participating in APCam01, aged 12 to 18 years, were recruited for APCam02. They were studied on two further occasions 1 to 4 weeks apart. On each occasion at 18:00, the subjects consumed either a rapidly or slowly absorbed large meal selected from a list of standardised meals differing in glycaemic load (113 +/- 29 versus 40 +/- 8; rapid versus slow, P = 0.001, paired t-test) but matched for carbohydrates (129 +/- 34 versus 129 +/- 34 g; P = NS). The carbohydrate amount corresponded to the largest meal eaten over the three preceding months.

Prandial insulin doses were comparable (17 ± 6 versus 17 ± 7 U) and were calculated according to subject's insulin-to-carbohydrate ratio. Closed-loop was performed from 18:30 to 08:00 the next day.

3. Effects of moderate-intensity evening exercise (APCam03):

Nine post-pubertal subjects aged 12 to 18 years were studied on two occasions 1 to 5 weeks apart; four subjects participated previously in APCam01. One week before the first study occasion, a ramped treadmill protocol was used to estimate the peak VO_2 as an indicator of the maximum oxygen uptake 15.

Subsequently, subjects were studied after identical exercise protocols using closed-loop or CSII. On each occasion at 16:00, subjects consumed a light meal chosen from a list of standardised snacks (45 ± 13 g carbohydrates) accompanied by prandial bolus calculated from subject's insulin-to-carbohydrate ratio. The subjects exercised at 55% $\text{VO}_{2\text{max}}$ on treadmill from 18:00 until 18:45 with a 5-minute rest at 18:20. Closed-loop was then performed overnight between 20:00 and 08:00. On the CSII night, subject's standard insulin pump settings were applied.

Intervention Type

Other

Phase

Phase II

Primary outcome(s)

Overnight glucose control including the assessment of variability and frequency of hypoglycaemic events.

Measured from the start of the closed-loop (20:00 or 18:30) until 08:00 the next day, and from 00:00 until 08:00 the day after.

Key secondary outcome(s)

1. The time spent in A+B and E+F Grades of the glycaemic control grading scheme
2. The total overnight insulin dose
3. Endocrine effects of exercise on growth hormone (GH), insulin-like growth factor 1 (IGF-1), insulin-like growth factor binding protein 1 (IGFBP-1) and counter-regulatory hormones

Measured from the start of the closed-loop (20:00 or 18:30) until 08:00 the next day, and from 00:00 until 08:00 the day after.

Completion date

23/09/2008

Eligibility

Key inclusion criteria

1. Young subjects stratified into age for each of the three trials:
 - 1.1. Trial 1: Aged 5 to 18 years, either sex
 - 1.2. Trial 2: Aged 12 to 18 years, either sex
 - 1.3. Trial 3: Aged Post-pubertal to 18 years, either sex
2. Type 1 diabetes for at least 6 months or confirmed C-peptide negative

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

5 Years

Upper age limit

18 Years

Sex

All

Key exclusion criteria

1. Any other physical or psychological disease or medication likely to interfere with the normal conduct of the study and interpretation of the study results
2. Experienced recurrent severe hypoglycaemic unawareness
3. Clinical significant nephropathy, neuropathy or proliferative retinopathy

Date of first enrolment

12/04/2007

Date of final enrolment

23/09/2008

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Department of Paediatrics

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge (UK)

ROR

<https://ror.org/04v54gj93>

Funder(s)**Funder type**

Charity

Funder Name

Juvenile Diabetes Research Foundation (UK) (ref: 22-2006-1113; 22-2007-1801)

Funder Name

European Foundation for Study of Diabetes (Germany)

Funder Name

Medical Research Council (MRC) (UK) - Centre for Obesity and Related metabolic Diseases (CORD)

Funder Name

National Institute for Health Research (NIHR) (UK) - Cambridge Biomedical Research Centre

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	27/02/2010		Yes	No
Results article	results	01/02/2011		Yes	No