

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

☐ Prospectively registered

☐ Protocol

Registration date
02/07/2009

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
27/04/2011

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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.

Study design

Phase II randomised controlled interventional crossover group trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 ± 23 g carbohydrates) at 18:00 accompanied by prandial insulin (9 ± 5 U) 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; $P = \text{NS}$). 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 measure

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.

Secondary outcome measures

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.

Overall study start date

12/04/2007

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

Age group

Child

Lower age limit

5 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

17

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

England

United Kingdom

Study participating centre
Department of Paediatrics
Cambridge
United Kingdom
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Sponsor information

Organisation

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

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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