ISRCTN18155883 https://doi.org/10.1186/ISRCTN18155883

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

Submission date
03/06/2009

Registration date
02/07/2009

Last Edited
27/04/2011

Recruitment status
No longer recruiting

Overall study status
Completed

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

Contact name
Prof David Dunger

Contact details
Department of Paediatrics
Box 116, Level 8 Addenbrooke's Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
dbd25@cam.ac.uk

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.

Study design
Phase II randomised controlled interventional crossover group trial

Primary study design
Interventional

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 VO2 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% VO2max 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