

Multicentre closed-loop home study in young people with type 1 diabetes

Submission date
16/01/2014

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
16/01/2014

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
21/01/2019

Condition category
Nutritional, Metabolic, Endocrine

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15892

Study information

Scientific Title

Multicentre closed-loop home study in young people with type 1 diabetes

Study objectives

An open-label, three-centre, randomised, two-period, crossover study to assess the efficacy, safety and utility of real-time continuous subcutaneous glucose monitoring combined with overnight closed-loop glucose control in the home setting in comparison with realtime continuous subcutaneous glucose monitoring alone in children and adolescents with type 1 diabetes on subcutaneous insulin infusion pump therapy

Ethics approval required

Old ethics approval format

Ethics approval(s)

13/EE/0120

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Topic: Diabetes Research Network, Medicines for Children Research Network; Subtopic: Type 1 , All Diagnoses; Disease: Diabetic Control, All Diseases

Interventions

1. Realtime CGM + overnight CL
2. Realtime CGM alone

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Time spent overnight in the target glucose range (3.9 to 8.0 mmol/l)

Secondary outcome measures

Not provided at time of registration

Overall study start date

10/12/2013

Completion date

31/12/2014

Eligibility

Key inclusion criteria

1. The subject is between 6 and 18 years of age (inclusive)
2. The subject has type 1 diabetes, as defined by WHO for at least 1 year or is confirmed C-peptide negative
3. The subject will have been an insulin pump user for at least 3 months, with good knowledge of insulin self-adjustment as judged by the investigator.
4. The subject is willing to perform regular fingerprick blood glucose monitoring, with at least 4 blood glucose measurements taken every day
5. HbA1c = 10 % based on analysis from central laboratory or equivalent
6. The subject is literate in English

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 24; UK Sample Size: 24

Key exclusion criteria

1. Known or suspected allergy against insulin
2. Nontype 1 diabetes mellitus including those secondary to chronic disease
3. Untreated celiac disease

4. Any other physical or psychological disease likely to interfere with the normal conduct of the study and interpretation of the study results as judged by the investigator
5. Current treatment with drugs known to interfere with glucose metabolism, eg systemic corticosteroids, nonselective betablockers and MAO inhibitors etc
6. Known or suspected allergy against insulin
7. Subjects with clinical significant nephropathy, neuropathy or proliferative retinopathy as judged by the investigator
8. Total daily insulin dose = 2 IU/kg/day
9. Total daily insulin dose < 10 IU/day
10. Pregnancy, planned pregnancy, or breast feeding
11. Severe visual impairment
12. Severe hearing impairment
13. Subjects using implanted internal pacemaker

Date of first enrolment

10/12/2013

Date of final enrolment

31/12/2014

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Wellcome Trust-MRC Institute of Metabolic Science

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospitals NHS Foundation Trust (UK)

Sponsor details

Children's Service

Box No 181

Addenbrookes Hospital

Hills Road

Cambridge
England
United Kingdom
CB2 0QQ

Sponsor type

Hospital/treatment centre

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Juvenile Diabetes Research Foundation Limited (JDRF) (UK)

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	26/11/2015	21/01/2019	Yes	No
HRA research summary			28/06/2023	No	No