ISRCTN24960600 https://doi.org/10.1186/ISRCTN24960600

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

Submission date	Recruitment status
16/01/2014	No longer recruiting
Registration date	**Overall study status**
16/01/2014	Completed
Last Edited	**Condition category**
21/01/2019	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
Ms Josephine Hayes

Contact details
Wellcome Trust-MRC Institute of Metabolic Science
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 1223 762 862
jfh31@cam.ac.uk

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment

Study type(s)
Treatment

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

Key secondary outcome(s)
Not provided at time of registration

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

Cpeptide
negative
3. The subject will have been an insulin pump user for at least 3 months, with good knowledge of insulin selfadjustment
as judged by theinvestigator.
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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
All

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
United Kingdom

England

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)

ROR
https://ror.org/04v54gj93

Funder(s)

Funder type
Charity

Funder Name
Juvenile Diabetes Research Foundation Limited (JDRF) (UK)

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