ISRCTN11496419 https://doi.org/10.1186/ISRCTN11496419

An open-label, single-centre, randomised, 2-period cross-over study to assess the efficacy and safety of a novel automated overnight closed-loop glucose control system on day 1 of continuous glucose monitoring sensor insertion in comparison to day 3 to 4 after sensor insertion in children and adolescents with type 1 diabetes

Submission date
30/01/2014

Recruitment status
No longer recruiting

Registration date
30/01/2014

Overall study status
Completed

Last Edited
09/08/2019

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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02129868

Secondary identifying numbers
16002

Study information

Scientific Title
An open-label, single-centre, randomised, 2-period cross-over study to assess the efficacy and safety of a novel automated overnight closed-loop glucose control system on day 1 of continuous glucose monitoring sensor insertion in comparison to day 3 to 4 after sensor insertion in children and adolescents with type 1 diabetes

Acronym
Automated closed-loop in children and adolescents with T1D

Study objectives
An openlabel, singlecentre, randomised, 2period crossover study to assess the efficacy and safety of a novel automated overnight closedloop glucose control system on day 1 of continuous glucose monitoring sensor insertion in comparison to day 3 to 4 after sensor insertion in children and adolescents with type 1 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ref: 13/WM/0498

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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: All Diseases, Device studies

Interventions
Primary Intervention, Sensor insertion for the Continuous Glucose monitor (CGM)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Primary Outcome; Timepoint(s): The primary outcome measure is time spent with plasma glucose concentration in the target range (3.9

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2014

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Between the ages of 6 and 18 years
2. Have Type 1 diabetes, as defined by WHO criteria for at least 1 year or is confirmed Cpeptide negative
3. Be an insulin pump user for at least 3 months, with a good knowledge of insulin dose adjustment
4. HbA1c between below 11 % based on analysis from central laboratory
5. Literate in English
6. Willing to undertake all study related activities

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: 12; UK Sample Size: 12

Key exclusion criteria
1. Nontype 1 diabetes mellitus including those secondary to chronic disease
2. Any other physical or psychological disease likely to interfere with the normal conduct of the study and interpretation of the study results
3. Current treatment with drugs known to interfere with glucose metabolism such as systemic corticosteroids, nonselective betablockers and MAO inhibitors
4. Known or suspected allergy against insulin
5. Subjects with clinically significant nephropathy, neuropathy or proliferative retinopathy as judged by the investigator
6. Patient is pregnant, or breast feeding during the period of the study
7. Total daily insulin dose = 2 Units/kg/day
8. Total daily insulin dose < 10 Units/day
9. Severe visual impairment
10. Severe hearing impairment
11. Subjects using implanted internal pacemaker

Date of first enrolment
01/01/2014

Date of final enrolment
01/09/2014

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
Research organisation

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	01/05/2017	21/01/2019	Yes	No
HRA research summary			28/06/2023	No	No