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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

Contact name
Ms Josephine Hayes

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

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02129868

Protocol serial number
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

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: All Diseases, Device studies

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

Intervention Type
Other

Phase
Not Applicable

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

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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
All

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
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
Research organisation

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