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	Recruitment status No longer recruiting	Prospectively registered		
30/01/2014		Protocol		
Registration date	Overall study status	Statistical analysis plan		
30/01/2014	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
09/08/2019	Nutritional, Metabolic, Endocrine			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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

Study design

Randomised; Interventional; Design type: Treatment

Primary study design

Interventional

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

Αll

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

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