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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
16/01/2014		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
16/01/2014	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
21/01/2019	Nutritional, Metabolic, Endocrine			

#### Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Ms Josephine Hayes

#### Contact details

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## 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

#### 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: 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

CB2 0QQ

Study participating centre
Wellcome Trust-MRC Institute of Metabolic Science
Cambridge
United Kingdom

## 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