Closed Loop In Pregnancy: normal daily activities study

[] Prospectively registered Submission date Recruitment status 09/02/2010 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 06/04/2010 Completed [X] Results [] Individual participant data **Last Edited** Condition category 12/07/2013 Nutritional, Metabolic, Endocrine

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Helen R Murphy

Contact details

Level 4 Metabolic Research Laboratories Institute of Metabolic Science Box 289 Addenbrookes Hospital Hills Road Cambridge United Kingdom CB2 0QQ +44 (0)1223 769079 hm386@medschl.cam.ac.uk

Additional identifiers

Protocol serial number

Version 1.2 Nov 11 2009

Study information

Scientific Title

Evaluation of the safety and efficacy of closed loop glucose control during the activities of normal daily living in women with type 1 diabetes during pregnancy: an open label randomised cross-over study

Acronym

CLIP - 02

Study objectives

Null hypothesis:

The computer-based closed loop (CL) system provides glucose control which is as safe and efficacious as conventional insulin pump therapy during pregnancy in women with type 1 diabetes.

Alternative hypothesis:

The computer-based closed loop (CL) system provides better glucose control and reduced risk of hypoglycaemia than conventional insulin pump therapy during pregnancy in women with type 1 diabetes.

A pilot feasibility study of this trial was performed in 2009, registered with an ISRCTN under the title 'Closed Loop In Pregnancy: evaluation of the gut absorption rate of glucose during an evening meal and breakfast in women with type 1 diabetes throughout pregnancy (CLIP -01)', and this record can be found at http://www.controlled-trials.com/ISRCTN62568875.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Essex 2 Research Ethics Committee approved on the 9th December 2009 (ref: 09/H0302/113)

Study design

Open label randomised cross-over study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 1 diabetes

Interventions

Treatment arm: 24 hours closed loop insulin delivery (dose titration by computer algorithm) Control arm: 24 hours of conventional insulin pump delivery (i.e dose titration according to fingerprick glucose levels)

Intervention Type

Other

Phase

Primary outcome(s)

Time spent with plasma glucose concentration in the target range (3.5 - 7.8 mmol/L) between 14.00 - 12.30 hours. Specific parameters will be the assessment of variability and frequency of mild and moderate hypoglycaemic events (plasma glucose less than 3.5 mmol/L and less than 2.8 mmol/L respectively), mild and moderate hyperglycaemic events (plasma glucose greater than 7.8 mmol/L and greater than 10.0 mmol/L respectively).

Key secondary outcome(s))

- 1. Total daily dose of insulin (TDD) on intervention versus control visit
- 2. Actiheart physical activity energy expenditure (PAEE) score during the 24 hour study visit and 24 hour free living
- 3. Continuous blood glucose monitored (CGM) glucose levels during the 24 hour study visit and 24 hour free living

Completion date

28/02/2011

Eligibility

Key inclusion criteria

- 1. Signed informed consent obtained before study-related activities. Study-related activities are any procedure that would not have been performed during standard medical care.
- 2. The participant is between 16 and 44 years of age (inclusive), female only
- 3. The participant has type 1 diabetes (T1DM), as defined by World Health Organisation (WHO) for at least 12 months and has had a viable singleton pregnancy confirmed by ultrasound
- 4. The participant has been commenced on insulin pump therapy during or prior to pregnancy
- 5. The participant is able and willing to use a real time continuous sensor

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

- 1. Non-type 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 such as coeliac disease or untreated hypothyroidism
- 3. Current treatment with drugs known to interfere with glucose metabolism such as systemic corticosteroids, non-selective beta-blockers and monoamine oxidase (MAO) inhibitors
- 4. Known or suspected allergy against insulin
- 5. Women with clinically significant nephropathy, neuropathy or proliferative retinopathy as

judged by the investigator

- 6. Documented gastroparesis
- 7. Very poor glycaemic control i.e. HbA1c greater than or equal to 10%
- 8. Significant obesity, i.e., body mass index (BMI) at booking greater than 35 kg/m^2
- 9. Total daily insulin dose greater than 1.5 IU/kg at booking
- 10. Women who have conceived with in vitro fertilisation (IVF) or assisted reproductive techniques

Date of first enrolment

01/03/2010

Date of final enrolment

28/02/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Level 4 Metabolic Research Laboratories Cambridge United Kingdom CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospital NHS Foundation Trust (UK)

ROR

https://ror.org/04v54gj93

Funder(s)

Funder type

Charity

Funder Name

Diabetes UK (UK) (ref: BDA 07/0003551)

Alternative Name(s)

DIABETES UK LIMITED, British Diabetic Association

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

National Institute for Health Research (NIHR) (UK) - Post-Doctoral Fellowship (ref: PDF/08/01/036)

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 adde	d Peer reviewed	? Patient-facing?
Results article	results	01/12/2011	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	5 No	Yes