ISRCTN50385583 https://doi.org/10.1186/ISRCTN50385583

Closed Loop In Pregnancy: normal daily activities study

Submission date	Recruitment status
09/02/2010	No longer recruiting
Registration date	**Overall study status**
06/04/2010	Completed
Last Edited	**Condition category**
12/07/2013	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

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)

Primary study design
Interventional

Study design
Open label randomised cross-over study

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

Phase II

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)
The British Diabetic Association, 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 added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2011		Yes	No