

Closed Loop In Pregnancy: normal daily activities study

Submission date 09/02/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 06/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/07/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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).

Secondary outcome measures

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

Overall study start date

01/03/2010

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

Age group

Adult

Sex

Female

Target number of participants

12

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/m²
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

England

United Kingdom

Study participating centre

Level 4 Metabolic Research Laboratories

Cambridge

United Kingdom

CB2 0QQ

Sponsor information

Organisation

Cambridge University Hospital NHS Foundation Trust (UK)

Sponsor details

Addenbrookes Hospital
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United Kingdom
CB2 0QQ
stephen.kelleher@addenbrookes.nhs.uk

Sponsor type

Hospital/treatment centre

Website

http://www.cuh.org.uk/addenbrookes/addenbrookes_index.html

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

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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