ISRCTN62568875 https://doi.org/10.1186/ISRCTN62568875

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

Submission date
03/06/2009

Recruitment status
No longer recruiting

Registration date
07/10/2009

Overall study status
Completed

Last Edited
20/11/2012

Condition category
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 1.3 Feb 9th 2009

Study information

Scientific Title
Evaluation of the gut absorption rate of glucose during an evening meal and breakfast: a prospective three-centre observational cohort study in pregnant women with type 1 diabetes

Acronym
CLIP - 01

Study objectives
We aim to evaluate whether estimates of glucose absorption rates differ according to the meal type and composition (i.e., breakfast versus evening meal) and according to gestational age during pregnancy. This evaluation will inform the future development of insulin dose adjustment algorithms for use in closed loop systems during pregnancy in women with type 1 diabetes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 1 Research Ethics Committee approved on the 16th December 2008 (ref: 08 /H0304/128)

Study design
Prospective multicentre observational cohort study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Pregnant women with pre-existing type 1 diabetes

Interventions
The same study protocol will be performed on two occasions during early (12 - 16 weeks gestation) and late (28 - 32 weeks gestation) pregnancy. On each occasion participants will eat a tracer-enriched, more slowly-absorbed evening meal, followed by an overnight stay with a tracer enriched, more rapidly absorbed breakfast meal the next morning. A variable subcutaneous (SC) insulin infusion will continue throughout using algorithm control aiming to maintain plasma glucose between 3.5 - 7.8 mmol/L.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)

Document the changes in gut absorption of a more slowly absorbed medium sized evening meal and a more rapidly absorbed medium sized breakfast meal during pregnancy by the model-based analysis of the data using computational approach previously described by Hovorka et al. The gut absorption rates will be compared using the root mean square error (RMSE).

Key secondary outcome(s))
Metrics obtained by modelling of tracer glucose:
1. BIOmod*: meal bioavailability
2. Tmax, mod*: time-to-maximum of the model-derived gut absorption
3. T25%, mod*, T50%, mod*, T75%, mod*: time to 25%, 50%, and 75% of the model-derived gut absorption
4. AUC0-420, mod*: the area-under-curve of the model-derived gut absorption

Analysis of plasma glucose:
5. Cmax,PG, tmax, PG: the concentration-time profile of plasma glucose concentration following meal digestion/start of glucose infusion

Analysis of plasma insulin:
6. AUCPI(0-240), Cmax, PI, tmax, PI for the concentration-time profiles of plasma insulin

Completion date
20/03/2010

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)
3. The participant has type 1 diabetes, as defined by World Health Organization (WHO) for at least 12 months and has had a viable singleton pregnancy confirmed by ultrasound
4. The participant has been on insulin pump or multiple daily injection (MDI) therapy for at least 6 months
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
20/03/2009

Date of final enrolment
20/03/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Cambridge Metabolic Research Laboratories
Cambridge
United Kingdom
CB2 0QQ

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge (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	01/02/2012		Yes	No
Results article	results	01/10/2012		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes