

A randomised controlled trial to evaluate the role of the continuous glucose monitoring system (CGMS) in pregnancies complicated by pre-existing diabetes

Submission date
30/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
30/09/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
07/10/2008

Condition category
Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0254145814

Study information

Scientific Title

Study objectives

The principal question is whether more detailed assessment of blood glucose levels using the CGMS system will improve glycaemic control throughout pregnancy without an excessive increase in rates of hyperglycaemia and thereby reduce both maternal and perinatal morbidity. In addition this will allow us to assess the relative contribution of different blood glucose parameters i.e. fasting Vs postprandial to measures of glycaemia (HbA1c) and foetal growth throughout gestation and neonatal hyperinsulinemia. The effects of intensive monitoring on self-efficacy and quality of life will also be measured. We will also examine in more detail then hitherto possible the frequency, severity and management of hypoglycaemia in pregnancy. A detailed economic evaluation of the costs and benefits of the intervention will also be a vital component of this study.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Collaborative, open-label, randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Nutritional, Metabolic, Endocrine: Diabetes

Interventions

A collaborative, open-label, randomised controlled trial with participants allocated to either standard antenatal care or CGMS which will be performed monthly in addition to standard care.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Infants:

1. Perinatal outcome assessed will be gestational age
2. Body weight
3. Respiratory distress (1 and 5 minute apgar scores)
4. Admission to special care baby unit with hypoglycaemia or hyperbilirubinaemia
5. Cord blood measurements of adiposity and hyperinsulinaemia

Mothers:

1. Glycaemic control
2. Frequency and severity of hypoglycaemia
3. Presence and /or progression of retinopathy
4. Mode of delivery
5. Delivery related complications
6. Diabetes related distress questionnaire
7. Individually generated index of quality of life measure

Secondary outcome measures

Not provided at time of registration

Overall study start date

08/04/2004

Completion date

31/12/2007

Eligibility**Key inclusion criteria**

Target total across all sites = 120.

Inclusion: All women with pre-existing diabetes attending Ipswich or Norwich antenatal diabetes centre.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

120 - closed to recruitment

Key exclusion criteria

None other than serious medical or psychological co-morbidity which would interfere with the subjects ability to participate.

Date of first enrolment

08/04/2004

Date of final enrolment

31/12/2007

Locations**Countries of recruitment**

England

United Kingdom

Study participating centre

The Ipswich Hospital NHS Trust

Ipswich

United Kingdom

IP4 5PD

Sponsor information**Organisation**

Department of Health

Sponsor details

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Ipswich Hospital NHS Trust (UK) NHS R&D Support Funding

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	25/09/2008		Yes	No