

# 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

**Registration date**

30/09/2005

**Overall study status**

Completed

**Last Edited**

07/10/2008

**Condition category**

Nutritional, Metabolic, Endocrine

☐ Prospectively registered

☐ Protocol

☐ Statistical analysis plan

☒ 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**

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 than 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

### Study type(s)

Not Specified

### 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(s)

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

**Key secondary outcome(s))**

Not provided at time of registration

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Female

**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**

United Kingdom

England

**Study participating centre**  
**The Ipswich Hospital NHS Trust**  
Ipswich  
United Kingdom  
IP4 5PD

## Sponsor information

**Organisation**  
Department of Health

## Funder(s)

**Funder type**  
Government

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

## 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?
<a href="#">Results article</a>	Results	25/09/2008		Yes	No