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Oral glucose tolerance test in first trimester of pregnancy

Submission date	Recruitment status	[X] Prospectively registered
20/01/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/03/2016	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Gestational diabetes is a type of diabetes that some women develop during pregnancy. It happens when there is too much sugar (glucose) in the blood. Normally, the amount of glucose in the blood is controlled by a hormone called insulin. However during pregnancy, some women have high levels of glucose in their blood that insulin cannot control. This can happen in as many as 1 in 20 pregnancies and can be linked with complications at birth and long term problems for mother and baby. The main way to treat gestational diabetes is by controlling blood sugar with a strict diet and exercise regime however some women need medication to keep their blood glucose under control. It usually develops in the third trimester (final part of pregnancy), however it is possible that it actually develops earlier. The main way of testing for gestational diabetes is by using the oral glucose tolerance test (OGTT). This test is usually carried out when a woman is between 24 and 28 weeks pregnant, however by this time in pregnancy, it can lead to serious complications. The aim of this study is to find out whether it would be possible to complete an OGTT on pregnant women who are between 11 and 14 weeks pregnant.

Who can participate?
Women over 18 years old, who are 11-14 weeks pregnant.

What does the study involve?
All women are asked not to eat or drink anything other than water for 12 hours before the test (overnight fasting). When the participants arrive for the test, a blood sample is taken in order to get a baseline (starting) measurement to compare the results of the OGTT to. The participants are then asked to drink a sweet liquid containing a specific amount of glucose and a further blood sample is taken at 1 and 2 hours. The number of participants who successfully complete the testing are then recorded.

What are the possible benefits and risks of participating?
Participants may benefit from an earlier diagnosis of gestational diabetes and so they would be able to be treated sooner than they would otherwise. There are no risks of taking part in this study, although participants may experience pain or bruising when having blood taken.

Where is the study run from?
Southend University Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2016 to September 2016

Who is funding the study?
Southend University Hospital NHS Foundation Trust (UK)

Who is the main contact?
Mr Mandeep Singh

Contact information

Type(s)
Scientific

Contact name
Mr Mandeep Singh

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Single center study to assess the feasibility of undertaking an oral glucose tolerance test in first trimester of pregnancy

Study objectives
Oral glucose tolerance test can be performed in first trimester (11- 14 weeks) of pregnancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales Research Ethics Committee 6 Proportionate Review Sub-Committee, 02/02/2016, ref: 16 /WA/0056

Study design
Single-centre cross sectional feasibility study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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
Gestational diabetes

Interventions
After fasting for 8-12 hours pre-test before a fasting blood glucose measurement is taken. Participants then consume a drink containing 75g glucose and blood glucose measurements are repeated at 1 and 2 hours.
No further follow up is needed. The blood results will be reviewed and is found abnormal then treatment will be planned as usual.

Intervention Type
Other

Primary outcome measure
Rate of successful completion of OGTT, as defined as the percentage of participants who complete the intervention, is determined at the end of the study period.

Secondary outcome measures
N/A

Overall study start date

01/01/2016

Completion date
01/06/2016

Eligibility

Key inclusion criteria
1. Female participants
2. Pregnancy between 11-14 weeks gestation confirmed by ultrasound scan
3. Able to give informed consent
4. Aged 18 years or over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
50

Key exclusion criteria
1. Pre-existing diabetes
2. Unable to provide informed consent
3. Under 18 years of age
4. Hyperemesis gravidum

Date of first enrolment
10/02/2016

Date of final enrolment
01/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Southend University Hospital NHS Foundation Trust
Prittlewell Chase
Westcliff on Sea
United Kingdom
SS0 0RY

Sponsor information

Organisation
Southend Hospital NHS Foundation Trust

Sponsor details
Prittlewell Chase
Westcliff on Sea
England
United Kingdom
SS0 0RY

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05fa42p74

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Southend Hospital NHS Foundation Trust

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
30/09/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			26/07/2023	No	No