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Screening for gestational diabetes: a randomised clinical trial of two universal methods

Submission date
13/09/2019

Recruitment status
No longer recruiting

Registration date
07/10/2019

Overall study status
Completed

Last Edited
03/10/2019

Condition category
Pregnancy and Childbirth

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
During pregnancy blood sugar levels become higher than normal in one eighth of Irish women. The term gestational diabetes is used to describe this elevation in sugar levels. Women with gestational diabetes, compared to women without gestational diabetes, have a higher risk of pregnancy complications such as preeclampsia in the mother and baby shoulder damage during delivery. Keeping the blood sugar levels in the normal range decreases the risk of pregnancy complications.

We wish to compare the two methods for screening for gestational diabetes.
- The oral glucose tolerance test is one of the methods. This involves an overnight fast of at least twelve hours, blood sampling before ingestion of 75 grams of glucose and blood sampling one and two hours afterwards.
- The glucose challenge test is the other method. No fast is involved in this test - a sample of blood is taken one hour after ingestion of 50 grams of glucose.

Who can participate?
All pregnant women aged 18-45

What does the study involve?
We will allocate randomly at least 600 women to undergo screening for gestational diabetes by either the oral glucose tolerance test or by the glucose challenge test. Women who chose not to participate in this study will continue to have standard obstetric care in Midland Regional Hospital Mullingar which involves a 75 gram oral glucose tolerance test if a risk factor for gestational diabetes is present.

We will determine glucose levels in women who agree to participate in this study by taking a blood sample upon study entry and again 21 weeks later (1-2 weeks before the estimated date of delivery). We will assess also quality of life and cost as well as the health of mothers and children.

What are the possible benefits and risks of participating?
Participants will not directly benefit by involvement in this research study. The knowledge gained from this study will inform management of other pregnant women in the future. If the one test is found to be preferable this will benefit the obstetric service offered in the MRHM.

The only potential risk is from the discomfort of venepuncture and possible bruising from the venepuncture site but this is non- serious and transient as is evident from their use in routine care. The national standard of care, currently offered by this obstetric service, will still be provided for every participant.

Where is the study run from?
Midland Regional Hospital Mullingar Hospital, Ireland

When is the study starting and how long is it expected to run for?
October 2013 to November 2015

Who is funding the study?
Midlands Regional Hospital Mullingar Diabetes Account

Who is the main contact?
Dr Tomas Ahern
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Screening for gestational diabetes: a randomised clinical trial comparing the glucose challenge test and the oral glucose tolerance test

Study objectives
Gestational diabetes is a state of hyperglycaemia, which affects 18% of pregnancies and can lead to a plethora of maternal and foetal complications. The risks of GDM can be mitigated by optimising glycaemia.

Although universal screening for GDM is accepted generally as desirable, the best strategy for GDM screening and diagnosis remains to be determined. The American Diabetes Association (ADA) and the International Association of Diabetes and Pregnancy Study (IADPSG) endorse use of the 75 g oral glucose tolerance test (OGTT) for screening. The American College of Obstetrics and Gynaecology (ACOG) on the other hand, recommends screening with the 50 g glucose challenge test (GCT) as part of a two-stage process involving a 100 g oral glucose tolerance test for those with a positive GCT.

The researchers plan to compare these two methods for screening for gestational diabetes. If they find that the glucose challenge test is as good, or is better, than the oral glucose tolerance test at ensuring good pregnancy outcomes, this will lead to a meaningful improvement in how pregnant women are managed in the future.

The hypothesis is that the rate of unfavourable pregnancy outcomes is lower with GCT screening than with OGTT screening.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/09/2013, Research Ethics Committee, Health Service Executive - Midland Area (HSE Area Offices, Arden Road, Tullamore, Co. Offally, Ireland; +353 579359894; paul.marsden@hse.ie), ref: 040913MG

Study design
Single-centre 24-week prospective parallel-arm clinical trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Gestational diabetes

Interventions
The interventions involved in this trial are the two methods of screening for gestational diabetes:
1. The oral glucose tolerance test involves an overnight fast of at least 12 hours, blood sampling before ingestion of 75 g of glucose and blood sampling 1 and 2 hours afterwards. Use of the oral

glucose tolerance test is recommended by the American Diabetes Association and by the International Association of Diabetes and Pregnancy Study Group.
2. The glucose challenge test is the other method. No fast is involved. A sample of blood is taken one hour after ingestion of 50 g of glucose. Use of the glucose challenge test is recommended by the American College of Obstetrics and Gynaecology as part of a two-stage process where those with a positive glucose tolerance test go on to have a 100 g oral glucose tolerance test.

The researchers randomly allocate 600 women to undergo screening for gestational diabetes by either the oral glucose tolerance test or by the glucose challenge test. Women who choose not to participate in this study will continue to receive the standard obstetric care in this centre (which involves a 75 g oral glucose tolerance test if a risk factor for gestational diabetes is present.)

The glucose levels in women who agree to participate in this study will be taken upon study entry and again 21 weeks later (1-2 weeks before the estimated date of delivery).

Intervention Type
Other

Primary outcome(s)
Maternal blood glycated haemoglobin level (HbA1c) at 16 and 36 weeks gestation

Key secondary outcome(s))
1. Maternal quality of life measured using PES scale, DASS, PSSS, EQ5D
2. Cost (attendance for GDM screening, attendance for prenatal visits, number of prenatal visits)
3. Fetal and neonatal parameters (large-for-gestational-age, birth weight> 4 kg, shoulder dystocia, bone fracture, nerve palsy, stillbirth, perinatal death, hypoglycaemia, weight, jaundice, admission to the special care baby unit)
4. Maternal and delivery parameters (gestational hypertension, pre-eclampsia, eclampsia, gestational diabetes, hypoglycaemia, HbA1c >5.6%, receipt of nutritional counselling, use of glucose-lowering therapies, blood pressure, weight gain, induction of labour, caesarean delivery)

Completion date
23/05/2016

Eligibility

Key inclusion criteria
All pregnant women aged 18-45

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Upper age limit
45 years

Sex
Female

Total final enrolment
600

Key exclusion criteria
1. Previous diagnosis of diabetes
2. Use of insulin
3. HbA1C>6.5%
4. Inability to give informed consent

Date of first enrolment
02/10/2013

Date of final enrolment
11/11/2015

Locations

Countries of recruitment
Ireland

Study participating centre
Midland Regional Hospital Mullingar Hospital
Co. Westmeath
Mullingar
Ireland
N91 NA43

Sponsor information

Organisation
Our Lady of Lourdes Hospital

ROR
https://ror.org/029sr1j73

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Midlands Regional Hospital Mullingar Diabetes Account

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository. https://data.mendeley.com/datasets/tdnt9xvmr5/draft?a=fbf623af-8c81-407e-a6fa-ace8ab941c9a
This link will work (and allow you to download the database) for the next three months (as of 01/10/2019)

IPD sharing plan summary
Available on request