ISRCTN16416602 https://doi.org/10.1186/ISRCTN16416602

Proinsulin in gestational diabetes mellitus

Submission date
03/10/2017

Recruitment status
No longer recruiting

Registration date
11/10/2017

Overall study status
Completed

Last Edited
21/10/2019

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
In pregnancy, some women are unable to process glucose (sugar) properly - this is referred to as gestational diabetes mellitus. It is a condition that is present only in pregnancy and the glucose levels usually return to normal after the birth of the baby. Gestational diabetes mellitus is linked with an increased risk of complications to both the baby (large baby, shoulder getting stuck in the birth canal and stillbirth) and the mother (prolonged labour). It is therefore important to screen and diagnose the condition, and early diagnosis and management has been shown to reduce the complications by up to 60%. Currently, at 24-28 weeks women with a risk factor (body mass index greater than 30 kg/m2, family history of diabetes in a first degree relative, previous history of diabetes or previous large baby i.e. birth weight >4.5 kg) are offered an oral glucose tolerance test (a glucose drink) with blood samples taken before and 2 hours after the drink. In this study the same test (oral glucose tolerance test) is done but at an earlier stage of pregnancy (at 16-18 weeks) in addition to the recommended test at 24-28 weeks to see if this new test is able to diagnose the condition at an earlier stage in pregnancy. Additional blood samples are also taken for measurement of beta cell function. The beta cells of the pancreas are responsible for controlling blood sugar by secretion of insulin. They also secrete very small amounts of proinsulin (which is normally converted to insulin inside the beta cells). Proinsulin is normally released in small quantities but concentrations increase with the onset of diabetes before glucose levels rise. The aim of this study is to find out whether measurement of the concentration of proinsulin provides an earlier and accurate means of identifying gestational diabetes mellitus.

Who can participate?
Pregnant women at least 18 years of age at 16-18 weeks of pregnancy with any one of the following: body mass index greater than 30 kg/m2, family history of diabetes in a first degree relative, previous history of diabetes or previous large baby i.e. birth weight >4.5 kg

What does the study involve?
This study involves three visits for participants at different stages of pregnancy. At visit 1 (16-18 weeks of pregnancy) participants fast overnight and an oral glucose tolerance test is conducted, with blood samples taken at 0, 30, 60 and 120 minutes after consumption of a glucose drink. Visit 2 (24 - 28 weeks of pregnancy) is the same as visit 1 and includes an oral glucose tolerance test after an overnight fast. At visit 3 (6 weeks after delivery) participants are asked to attend after fasting overnight and have a fasting blood sample taken. Additional data are collected

including birth weight of the baby, Apgar score at birth and medications including insulin doses before birth.

What are the possible benefits and risks of participating?
If this test does prove useful, in future pregnant women can potentially be diagnosed with gestational diabetes mellitus at an earlier stage, reducing the risk of complications. It is not expected that participating in this study will cause any problems, but as blood samples are taken participants may experience bleeding, discomfort, bruising, infection or inflammation where the blood is taken or dizziness and feeling faint.

Where is the study run from?
Swansea University (UK)

When is the study starting and how long is it expected to run for?
October 2017 to August 2020

Who is funding the study?
Abertawe Bro Morgannwg University Health Board (UK)

Who is the main contact?
Sarah Dowrick
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

1.0

Study information

Scientific Title
Proinsulin in the diagnosis and risk stratification of gestational diabetes mellitus

Study objectives
The primary objective of this study is to test the hypothesis that fasting proinsulin measurements at 16-18 weeks gestation will discriminate/risk stratify gestational diabetes from women with normal glucose tolerance.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 6, 06/07/2017, ref: 17/WA/0194

Study design
Observational cross-sectional pilot study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
This study will involve three visits for participants, at different stages of gestation.
Visit 1 (16-18 weeks gestation): participants will be asked to attend at 16-18 weeks gestation, having fasted overnight. An oral glucose tolerance test will be conducted, with blood samples taken at 0, 30, 60 and 120 mins following consumption of a glucose drink.
Visit 2 (24 - 28 weeks gestation): this will be the same as visit one and include an oral glucose tolerance test after an overnight fast.
Visit 3 (6 weeks post delivery): participants will be asked to attend having fasted overnight and will have a fasting blood sample taken. Additional data including birth weight of the baby, Apgar score at birth and medications including insulin doses prior to birth will be collected.

Intervention Type
Other

Primary outcome measure
Circulating concentration of fasting total and intact proinsulin at 16-18 weeks gestation

Secondary outcome measures
1. Diagnosis of gestational diabetes mellitus as established by glucose measurements following an oral glucose tolerance test at 24-28 weeks
2. Need for insulin during the pregnancy obtained from clinical notes
3. Relationship between individual risk factors and proinsulin for the development of gestational diabetes mellitus, measured using logistic regression at 16-18 weeks

Overall study start date
01/10/2017

Completion date
01/08/2020

Eligibility

Key inclusion criteria
Pregnant women at least 18 years of age at 16-18 weeks gestation with any one of the following:
1. BMI >30kg/m2
2. Previous macrosomic baby (>4.5kg)
3. Previous gestational diabetes mellitus
4. Family history of type 2 diabetes mellitus (first degree relative with diabetes)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200

Key exclusion criteria
1. Subjects unable or unwilling to sign informed consent
2. Known previous diabetes mellitus or treatment with metformin
3. Known chronic infection like Hepatitis or HIV or chronic kidney, liver or heart disease
4. Previous bariatric surgery

Date of first enrolment

16/10/2017

Date of final enrolment
01/08/2020

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Joint Clinical Research Facility
Institute of Life Sciences 2
Swansea University
Swansea
United Kingdom
SA2 8PP

Sponsor information

Organisation
Abertawe Bro Morgannwg University Health Board

Sponsor details
ABMU Health Board Research & Development Department, ILS2
Swansea University
Swansea
Wales
United Kingdom
SA2 8PP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Abertawe Bro Morgannwg University Health Board

Results and Publications

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

Intention to publish date
01/08/2021

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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?
Protocol article	protocol	29/08/2018	21/10/2019	Yes	No
HRA research summary			28/06/2023	No	No