

Proinsulin in gestational diabetes mellitus

Submission date 03/10/2017	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 11/10/2017	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/09/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Total final enrolment

83

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
Results article		05/09/2025	09/09/2025	Yes	No