ISRCTN13935752 https://doi.org/10.1186/ISRCTN13935752

Using a blood test alongside body fat measurements for obesity risk prediction to improve pregnancy outcomes

Submission date
22/01/2026

Recruitment status
No longer recruiting

Registration date
06/03/2026

Overall study status
Ongoing

Last Edited
06/03/2026

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Increasing numbers of people experience pregnancy complications linked to the amount of body fat people have, and where abouts on their body fat is stored (known as adiposity). Risk prediction research helps to identify who is most likely to develop complications to help plan care. Current guidelines use body mass index (BMI), a measure of a person's height and weight, to assess risk and plan care. Our current research, called SHAPES, shows that using BMI misses half of the pregnant people who develop diabetes, and we need to find a better measure. We found that waist size and ultrasound scans of stomach fat worked better than BMI. Other studies show that using biomarkers (chemicals in the blood, like hormones) can improve risk prediction. This study aims to explore whether combining adiposity measures and biomarkers can help identify who will develop pregnancy complications.

Who can participate?
No new participants required. We use data and samples from the SHAPES study, which completed its recruitment in April 2024.

What does the study involve?
We will use SHAPES data on adiposity and pregnancy outcomes for SHAPES-Bio. We have permission from SHAPES research participants to use their existing blood samples to test for biomarkers. We will compare different combinations of biomarkers and adiposity measures (such as waist size or ultrasound scans of stomach fat) to see which combinations work best to predict pregnancy complications.

What are the possible benefits and risks of participating?
Not applicable as no participants were recruited for this study.

Where is the study run from?
Newcastle upon Tyne NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2022 to October 2026

Who is funding the study?
NIHR Research for Patient Benefit (RfPB) (UK)

Who is the main contact?
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Study information

Scientific Title
Using a blood test alongside body fat measurements for obesity risk prediction to improve pregnancy outcomes

Acronym
SHAPES-Bio

Study objectives
Determining whether adding biomarkers to adiposity risk prediction model(s) for pregnancy complications can
improve accuracy compared to current practice

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 18/06/2025, North East - Newcastle & North Tyneside 1 Research Ethics Committee (2nd Floor, 2 Redman Place, Stratford, E20 1JQ, United Kingdom; Not available; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 22/NE/0035

Primary study design
Observational

Secondary study design
Retrospective cohort study

Study type(s)

Health condition(s) or problem(s) studied
Pregnancy outcomes

Interventions

Data from the SHAPES study will be used, with serum samples from 885 participants. Biochemical measures will include a traditional lipid panel, adiponectin, gamma-glutamyl transferase, sex-hormone binding globulin, and ferritin. Robust predictive models will be built allowing for missing data and using resampling methods to calculate optimism-corrected performance. Decision curve analysis will compare the clinical net benefit of each model with current practice.

Intervention Type
Other

Primary outcome(s)
1. Gestational diabetes measured using fasting plasma glucose level of ≥5.6 mmol/litre or 2-hour plasma glucose level of ≥7.8 mmol/litre at gestation at diagnosis

Key secondary outcome(s))
1. Pre-term birth measured using birth before 37 weeks gestation at gestation at delivery

2. Late-term birth measured using pregnancy that extends over 41 weeks gestation at gestation at delivery

3. Induction of labour measured using non-surgical treatment to induce the labour at intrapartum

4. Caesarean section measured using surgical delivery of baby (emergency or elective) at intrapartum

5. Retained placenta measured using medical records at postnatal period

6. Haemorrhage measured using milliliters of blood loss at third stage of labour and immediate postpartum period

7. Maternal infection measured using medical records at antenatal, intrapartum and postnatal

8. Large for gestational age measured using birth weight above the 90th centile for gestational age and sex on INTERGROWTH chart at birth

9. Small for gestational age measured using birth weight below the 10th centile for gestational age and sex on INTERGROWTH chart at birth

10. Apgar scores at 1 and 5 minutes (score 1-10) measured using medical records at birth

11. Jaundice measured using medical records at birth

12. Feeding method measured using medical records at first feed and feed method at discharge

13. Admission to neonatal special care baby unit (SCBU) or intensive care unit (NICU), high-dependency care, transitional care measured using medical records at postnatal

14. Preeclampsia measured using a new onset of hypertension (>140 mmHg systolic or >90 mmHg diastolic) after 20 weeks of pregnancy with a new onset of proteinuria or/and maternal organ dysfunction or/and uteroplacental dysfunction. Early onset defined as onset of PE before 34 weeks gestation. at gestation of onset

Completion date
31/10/2026

Eligibility

Key inclusion criteria
1. Pregnant with a singleton pregnancy
2. Presenting to a scan at 11+2 to 14+1 weeks gestation
3. ≥18 years of age
4. Planned to deliver locally

Healthy volunteers allowed
Yes

Age group
Adult

Lower age limit
18 years

Upper age limit
60 years

Sex
All

Total final enrolment
885

Key exclusion criteria
1. Unable/unwilling to give informed consent to participate
2. Women with a miscarriage prior to the 12-week scan, or threatened miscarriage identified on the patient's records as a visit to the Early Pregnancy Assessment Clinic (EPAC) or A&E relating to their pregnancy with an adverse outcome, will be excluded.
3. Women having twins (or higher order pregnancy) - we will not know whether women have a multiple pregnancy until their 12-week scan appointment (after consent). Any women identified as having a multiple pregnancy at the 12-week scan will be excluded. They will still receive the thank-you gift of pregnancy photographs.

Date of first enrolment
28/04/2022

Date of final enrolment
04/04/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The Newcastle upon Tyne NHS Foundation Trust
The Reproductive Health & Neonates Research Team, Level 6, Leazes Wing, Royal Victoria Infirmary
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Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

ROR
https://ror.org/05p40t847

Funder(s)

Funder type

Funder Name
Research for Patient Benefit Programme

Alternative Name(s)
NIHR Research for Patient Benefit Programme, Research for Patient Benefit (RfPB), The NIHR Research for Patient Benefit (RfPB), RfPB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available