ISRCTN82185177 https://doi.org/10.1186/ISRCTN82185177

Does maternal body fat amount and location impact pregnancy health?

Submission date
01/03/2023

Recruitment status
No longer recruiting

Registration date
07/03/2023

Overall study status
Completed

Last Edited
07/03/2024

Condition category
Pregnancy and Childbirth

[_] 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
Having an obese body mass index (BMI greater than 30 kg/m²) in early pregnancy is associated with pregnancy complications including diabetes and preterm birth. Current guidelines recommend extra "high-risk" care is provided to try and manage obesity complications, including additional referrals, tests and monitoring. However, BMI isn't a very good measure to be able to accurately determine which women will develop complications during pregnancy. About half of women with obesity (87,000 women each year in England) don't develop any complications and don't need the high-risk care they receive, whereas about 40% of women without obesity (103,000 women) do develop these complications and do require high-risk care, but don't receive it as their BMI is not high enough. Fat stored in the upper body is associated with an increased risk of poor health. Someone with a "healthy" BMI who stores fat above their waist can have a higher risk than someone with a high BMI who stores fat below their waist. There are some measures (e.g. waist size, ultrasound examination) which can identify where body fat is stored and these may be better than BMI at identifying which pregnant women need high-risk care. This study will explore how accurate different measures are at predicting which women develop pregnancy complications to help target high-risk care to women who need it.

Who can participate?
Pregnant women who are planning on having their baby at Newcastle upon Tyne NHS Trust, aged 18 years or over, with a single pregnancy (one baby), between 11 weeks and 2 days and 14 weeks and 1 day pregnant.

What does the study involve?
The researchers will invite pregnant women to have measurements taken in early pregnancy during their routine dating scan appointment (around 12 weeks into their pregnancy). These measurements include additional ultrasound scans of fat around the stomach area, as well as the size of their waist, hips, upper arm, and neck and how much fat is stored under their skin (called skinfold thickness). The researchers will link this data with the pregnancy outcomes recorded routinely in women's maternity records. Statistical analysis will compare the different adiposity measures with BMI to explore which measures are best at predicting pregnancy complications.

What are the possible benefits and risks of participating?
There are no direct benefits for women taking part in this study. The results might inform changes to future care provision. Therefore any women who become pregnant again in the future could benefit from the research. The risks are minimal as this is a non-invasive observational study. The main research burden is that women will need to stay longer for their routine hospital appointment to have the extra measurements taken.

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

When is the study starting and how long is it expected to run for?
January 2019 to July 2025

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK)

Who is the main contact?
Dr Nicola Heslehurst, nicola.heslehurst@ncl.ac.uk

Study website
https://research.ncl.ac.uk/shapes/

Contact information

Type(s)
Scientific

Contact name
Dr Nicola Heslehurst

ORCID ID
http://orcid.org/0000-0001-8656-2319

Contact details
Population Health Sciences Institute
Baddiley Clark Building
Richardson Road
Newcastle University
Newcastle-Upon-Tyne
United Kingdom
NE2 4AX
+44 (0)1912083823
nicola.heslehurst@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

302444

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 51957, IRAS 302444

Study information

Scientific Title
Study of How Adiposity in Pregnancy has an Effect on outcomeS (SHAPES): a cohort study

Acronym
SHAPES

Study objectives
Early pregnancy adiposity measures will more accurately predict pregnancy risk than body mass index (BMI).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/02/2022, North East - Newcastle & North Tyneside 1 Research Ethics Committee NHSBT (Newcastle Blood Donor Centre, Holland Drive, Newcastle upon Tyne, NE2 4NQ, UK; +44 (0)2071048139, +44 (0)2071048255; newcastlenorthtyneside1.rec@hra.nhs.uk), ref: 22/NE/0035

Study design
Observational; Design type: Cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See trial outputs table

Health condition(s) or problem(s) studied
Adiposity in pregnancy

Interventions

All pregnant women who book their antenatal care with the Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH) are sent a research information letter outlining that NUTH is a research active Trust and women are likely to be approached by the clinical research team with information about relevant research projects. The researchers will add some brief information about the SHAPES study to this routine letter (which will be alongside brief information about other ongoing research at NUTH). The SHAPES information in the letter will indicate that women may be contacted by telephone by a member of the clinical research team to discuss the study and enquire if they are interested in taking part, or may be approached at their 12-week scan clinic appointment. The letter will make clear that women have the opportunity to opt out of being contacted either by calling or emailing a designated team member, as well as the opportunity to contact the team for more information regarding the project if they might be interested in taking part. At least one week will elapse between sending the research information letter and contact being made by telephone by the clinical research team to allow women to opt-out if they wish.

Prior to making first contact with potential participants, members of the dedicated clinical research team will check for women who have requested not to be contacted (opted out) or have a diagnosis of miscarriage, or have had a recent attendance at the early pregnancy assessment unit or A&E (signifying threatened miscarriage/early pregnancy complication). Women will be contacted by phone by a member of the clinical research team to book their routine 12-week scan appointment. During this call, the clinical team will discuss the SHAPES study and find out if they would potentially be interested in taking part. Women who indicate that they would potentially be interested in taking part will be sent (post or email) a participant information sheet (PIS) and offered an appointment for their first-trimester scan in a research ultrasound clinic embedded within the routine antenatal scan clinic.

Potential participants will have a further opportunity to discuss the study with a member of the research team when they attend for their scan appointment. They will also be able to contact the research team in advance of this appointment in case of additional queries if they want to. Women's care will not be affected irrespective of participation in the study; women who decline participation will still have their routine first-trimester scan performed as planned at this appointment.

Women who decide that they do want to participate will be asked to give written informed consent before having their scan appointment, prior to any research procedures being performed.

Participants' routine first-trimester scans will be performed by a research sonographer who is qualified to perform first-trimester ultrasound examination and screening and does this routinely as part of their clinical role. The sonographer will have the extra training required to also take the research ultrasound measurements required for the study. The additional ultrasound measurements required for the study will be taken at the end of the scan appointment upon completion of clinical examination and are subject to normal ultrasound finding procedures during this scan appointment. Once the ultrasound measurements and all other routine clinical procedures are completed, the rest of the study assessment and data collection will be performed by a trained member of the research team from Newcastle University or the clinical research team in NUTH.

As well as additional ultrasound measurements, participants will also have weight, height, waist circumference, hip circumference, neck circumference, mid upper arm circumference and skinfold thickness measurements taken. The research team will all have received ISAK training and accreditation; ISAK is the international body for training and accreditation of body

composition measurements. Each measurement will be repeated three times. The researchers will also ask participants to complete a questionnaire to provide information on their socio-demographic characteristics, medical history and visual body shape scale. They will request consent from participants to access their medical records after they have delivered their babies to obtain data on their pregnancy and its outcome. It is anticipated that the extra measurements required for the study will take an additional 45 minutes, above the time women would normally spend in the ante-natal clinic when attending for their first-trimester scan.

In addition, to taking part in the main study, participants will have the option of consenting to two additional elements of research. Participants can consent to both, either or none of these and still participate in the SHAPES Cohort Study.

These are:
1. The researchers will ask participants if they would like to share their contact details with the research team at Newcastle University in order to be contacted at a later date to be interviewed about their views on having the extra adiposity measurements taken. This extra study with a sub-group of approximately 30 women participating in the SHAPES study will be subject to a separate ethics application and consent process. At this stage, women will only be consenting to pass their contact details to the research team who may or may not contact them in the future about this qualitative research.
2. The researchers will ask participants if they would like to consent to long-term passive follow-up of their health and well-being through their medical records and access to health data stored routinely (for example GP records and NHS Digital data). This will require that they store their SHAPES participant ID number linked with their NHS number and their baby's NHS number. This is for the purpose of future data linkage studies which will allow us to explore whether adiposity measures in early pregnancy can be used to identify women and children at future risk of adverse health and wellbeing outcomes (e.g. does waist circumference or ultrasound scans of visceral fat thickness in the first trimester of pregnancy predict the risk of women or children developing type 2 diabetes in later life?). If the researchers do find that early pregnancy adiposity measurements are useful to identify women and children at increased risk in later life, then this could inform preventative intervention opportunities that could start in the postnatal period. Any future study using SHAPES-linked data will be subject to appropriate ethical and other research approvals required.

No other contact with participants will be required after their 12-week scan appointment, unless they agree to be contacted, and are selected, to be interviewed about their experience of having the extra measures taken.

Intervention Type
Other

Primary outcome measure
All outcomes are collected from routine maternity records following birth:
1. Gestational diabetes: fasting plasma glucose level of ≥ 5.6 mmol/litre or 2-hour plasma glucose level of ≥7.8 mmol/litre
2. Preeclampsia (PE): 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.
3. Pre-term birth: birth before 37 weeks gestation
4. Small for gestational age: birth weight below the 10th centile for gestational age and sex on

INTERGROWTH chart
5. Large for gestational age: birth weight above the 90th centile for gestational age and sex on INTERGROWTH chart
6. Caesarean section: surgical delivery of baby (emergency or elective)

Secondary outcome measures
All outcomes collected from routine maternity records following birth:
1. Gestational hypertension: blood pressure ≥140/90 mmHg on two occasions at least 4 hours apart after 20 weeks gestation
2. Late-term birth: pregnancy that extends over 41 weeks gestation
3. Induction of labour: non-surgical treatment to induce the labour
4. Instrumental delivery: an assisted birth when forceps or a ventouse suction cup is applied
5. Retained placenta: as reported in medical records
6. Haemorrhage: 3rd stage of labour and immediate postpartum period, measured in ml blood loss; as reported in medical records
7. Maternal infection: as reported in medical records
8. Fetal growth: measured at 2nd and 3rd trimester scans, including:
8.1. 2nd trimester scan: fetal head circumference; fetal abdominal circumference; fetal femur length; estimated fetal weight Hadlock; as reported in medical records
8.2. 3rd trimester scan: abdominal circumference; femur length; estimated fetal weight Hadlock; umbilical artery PI; end diastolic flow; amniotic fluid index; as reported in medical records
9. Apgar scores at 1 and 5 minutes (score 1-10): as reported in medical records
10. Respiratory distress (including requiring resuscitation): as reported in medical records
11. Feeding method (first feed and feed method at discharge): breastfeeding or artificial feed; as reported in medical records
12. Admission to neonatal special care baby unit (SCBU) or intensive care unit (NICU), high-dependency care, transitional care: as reported in medical records

Overall study start date
01/01/2019

Completion date
31/07/2025

Eligibility

Key inclusion criteria
1. Singleton pregnancy (women who consent to participate but who are subsequently found to have a multiple pregnancy will be excluded)
2. ≥18 years of age
3. Approximately 12 weeks' gestation (11+2 to 14+1 weeks)
4. Planned delivery at NUTH

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 1400; UK Sample Size: 1400

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

Date of first enrolment
16/03/2022

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
TS1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Freeman Hospital
Freeman Road
High Heaton

Newcastle-Upon-Tyne
England
United Kingdom
NE7 7DN
+44 (0)191 282 4516
judith.marston2@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
NIHR Academy; Grant Codes: CDF-2018-11-ST2-011

Results and Publications

Publication and dissemination plan
Planned publication in high impact peer-reviewed journals within 1 year of the trial end date

Intention to publish date
31/07/2026

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?
Participant information sheet	version 2.2	17/10/2022	03/03/2023	No	Yes
Protocol file	version 3.5	01/12/2022	03/03/2023	No	No
HRA research summary			28/06/2023	No	No

Protocol article	12/09/2023	14/09/2023	Yes	No