ISRCTN41944844 https://doi.org/10.1186/ISRCTN41944844

Understanding the relationship between uterine artery Doppler measurements (blood flow to the placenta) and aspirin response

Submission date
16/04/2019

Recruitment status
No longer recruiting

Registration date
23/04/2019

Overall study status
Completed

Last Edited
10/05/2024

Condition category
Pregnancy and Childbirth

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

Plain English Summary

Background and study aims
Abnormal development of the placenta (afterbirth) can cause serious pregnancy complications such as abruption, preeclampsia, and small for gestational age (SGA) (complications also known as Placenta Mediated Disease [PMD]). PMD can lead to devastating pregnancy outcomes such as the mother and baby's death as well as affect the mother's and baby's health later in life. Thus prediction and prevention of PMD remains a high priority for researchers and clinicians worldwide. Currently, all women deemed to be at increased risk for PMD are offered a low dose of aspirin as a preventative measure. Unfortunately humans process aspirin differently so the effectiveness of this preventative treatment varies. A simple ultrasound assessment of the blood flow in the womb arteries performed at the time of 20 weeks scan has been shown to be a good predictor of poor pregnancy outcome. However, the clinical importance of such assessment in women receiving aspirin therapy is unclear. This study will explore the change (worsening or improvement) in the blood flow through the womb arteries from the start of aspirin treatment to the mid-point of pregnancy in those who respond to the treatment and those who do not. Women's response to aspirin will be checked by a blood test.

Who can participate?
Women at risk of preeclampsia

What does the study involve?
Participants are asked to provide information about their health at the first study visit. Then the blood flow to the uterus (womb) is measured using ultrasound. This examination is painless and takes only a few minutes to perform. During the participant's second visit at the time of a routine 20 weeks scan, the ultrasound measurement is repeated, and participants are asked to provide a urine sample and about 10 ml of blood (about two teaspoons). The blood and urine are tested in the hospital laboratory to see if the participants have responded to aspirin. This is done at a later date as it is not a routine test. The results will therefore not be available to participants.

What are the possible benefits and risks of participating?
There are no direct benefits to participants from the study. It is anticipated that the information gained from participation in this study will help to improve the care of women with a high risk of developing placenta-mediated disease in the future. The results of this study may allow a better understanding of aspirin's role in preventing PMD and also may allow clinicians to detect non-responders who are more likely to develop PMD and in whom alternative treatment could be offered. The researchers do not anticipate that any harm will come to participants by taking part in this study as the only additional element is collecting blood and urine samples. This will be carried out by an experienced member of the research team.

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

When is the study starting and how long is it expected to run for?
May 2017 to October 2019

Who is funding the study?
College of Radiographers Industry Partnership Scheme Research Grants

Who is the main contact?
Raya Vinogradov
raya.vinogradov@ncl.ac.uk

Contact information

Type(s)
Public

Contact name
Mrs Raya Vinogradov

ORCID ID
http://orcid.org/0000-0001-9375-7915

Contact details
The Reproductive Research Team
Level 6, Leazes Wing
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP
+44 (0)191 2820540
raya.vinogradov@ncl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
V7 (03.10.2018)

Study information

Scientific Title
Sequential analysis of uterine artery Doppler waveforms in high-risk population for placenta-mediated disease undergoing prophylactic aspirin therapy controlled by levels of serum thromboxane

Acronym
Wave 1

Study hypothesis
Is the change in uterine artery pulsatility index between first and second trimester influenced by response to aspirin therapy (as determined by serum Tbx inhibition) in women at high risk of placenta-mediated disease?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/03/2017, East of Scotland Research Ethics Service, (Tayside Academic Health Sciences Centre, Residency Block Level 3, George Pirie Way, Ninewells Hospital & Medical School, Dundee, DD1 9SY, UK; Tel: +44 (0)1382 383871; Email: eosres.tayside@nhs.net), ref: 17/ES/0018

Study design
Observational study

Primary study design
Observational

Secondary study design

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format. Please call +44 (0)1912820540 to request a participant information sheet

Condition
Preeclampsia

Interventions
1. Change in the blood flow calculated from routine uterine artery Doppler examination at 12 and 20 weeks gestation
2. Urine and blood test at 20 weeks gestation looking at the levels of Thromboxane

Intervention Type
Other

Primary outcome measure
Level of serum Thromboxane B2 measured in blood at 20 weeks gestation

Secondary outcome measures
Pregnancy outcome (i.e. preeclampsia) at delivery of the baby

Overall study start date
08/05/2017

Overall study end date
21/10/2019

Eligibility

Participant inclusion criteria
Women at risk of preeclampsia according to NICE criteria

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
294

Total final enrolment
345

Participant exclusion criteria
Unable to give informed consent

Recruitment start date
01/06/2017

Recruitment end date

25/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle upon Tyne NHS Hospitals Foundation Trust
The Reproductive Research Team
Level 6, Leazes Wing
The Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust

Sponsor details
Newcastle Joint Research Office
Level 1 Regent Point
Regent Farm Road
Gosforth
Newcastle upon Tyne
England
United Kingdom
NE3 3HD
+44 (0)191 282 5959
trust.r&d@nuth.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/about-us/staff-information_research-development.aspx

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Other

Funder Name
College of Radiographers Industry Partnership Scheme Research Grants

Results and Publications

Publication and dissemination plan
1. Summary of the study protocol is available at: https://www.sor.org/system/files/article/201609/write_up_131.pdf
2. Peer reviewed journals and through relative charities (APEC)

Intention to publish date
01/05/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Raya Vinogradov (Raya.vinogradov@ncl.ac.uk) or Marc Davies (Marc.Davies@nuth.nhs.uk). The dataset is fully anonymised by assigning a study ID number to all participants. Only the clinical/research team is able to link the study ID to participant information. Data will be stored in line with the sponsor's requirements by the local trial coordinator upon completion of data collection, data query and analysis. Fully anonymised data will be analysed by a PI with support from a statistician from Newcastle University.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 7	03/10/2018	11/08/2022	No	No
HRA research summary			28/06/2023	No	No
Other publications	Aspirin non-adherence in pregnant women at risk of preeclampsia (ANA): a qualitative study	06/08/2021	10/05/2024	Yes	No