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Screening programme for pre-eclampsia

Submission date
23/05/2016

Recruitment status
No longer recruiting

Registration date
06/07/2016

Overall study status
Completed

Last Edited
18/08/2023

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Pre-eclampsia (PE) is a medical condition which can develop during pregnancy, and can affect both the mother and unborn baby. In PE, it is thought that the blood supply to the placenta (organ which connects the mother and child's blood supply) is reduced, which can mean the unborn baby does not get enough nutrients to develop properly. The key indicators of PE are high blood pressure and protein in the mother's urine. The National Institute for Health and Clinical Excellence (NICE) recommends that the way to determine whether a woman is at high-risk of developing pre-eclampsia should depend on maternal risk factors. However, this method of screening only identifies about 40% of the women that develop pre-eclampsia requiring delivery before 37 weeks and 35% of all cases of pre-eclampsia. This study uses a new method of screening called the Bayes method that combines maternal risk factors with the results from various tests to calculate the individual risk for developing pre-eclampsia. Extensive research in the last decade has led to the identification of four potentially useful tests: measurements of blood pressure, blood flow in the maternal blood vessels that supply the womb and the levels of two placental hormones in the mother's blood. There is some evidence that the new test used in this study is superior to that of NICE method. The aim of the study is to evaluate the effectiveness of this new method of screening for pre-eclampsia against that currently recommended by NICE.

Who can participate?
Pregnant women aged 18 years or over with a live fetus at 11-13 weeks pregnancy.

What does the study involve?
Women attend two study visits, one when they are 11-13 weeks pregnant and one when they are 19-24 weeks pregnant. At the first study visit, women have their weight and height recorded as well as their medical history. They then have a special ultrasound scan to measure the blood flow in the vessels that supply the womb and have samples of blood taken which are tested for placental hormones. At the second study visit, routine data is collected during the participants scan. The information collected at these visits is then used to make predictions about whether the women will develop pre-eclampsia. Women then have their medical records reviewed up to one month after they have had their baby to find out which screening method is most accurate.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
King’s College Hospital (lead centre) and six other hospitals in England (UK)

When is the study starting and how long is it expected to run for?
October 2015 to July 2018

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

Who is the main contact?
Dr Kate Maclagan
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Contact information

Type(s)
Scientific

Contact name
Dr Kate Maclagan

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20412

Study information

Scientific Title
The diagnostic accuracy of pregnant women screened for pre-eclampsia using Bayes theorem based and screening according to NICE guidelines

Acronym
SPREE

Study objectives
The aim of this study is to compare screening for pre-eclampsia (PE) using a Bayes theorem based method with screening using current NICE guidelines.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London- Surrey Borders Research Ethics Committee, 22/12/2015, ref: 15/LO/2161

Study design
Observational diagnostic accuracy cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

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
Specialty: Reproductive health and childbirth, Primary sub-specialty: Reproductive and sexual medicine

Interventions
All participants to attend the 2 study visits (at 11-13 weeks gestation and 19-24 weeks gestation). The final, pregnancy outcome data is retrieved from patient notes so no participant visit is required.

At the first study visit women will give informed consent, and data will be collected on patient demographics, height and weight, maternal medical and obstetric history, family history, drug history including aspirin intake, routine first-trimester scan, mean arterial pressure, uterine artery blood flow(pulsatility index) via transabdominal colour Doppler ultrasound. Blood samples will also be collected to measure for biomarkers serum placental growth factor (PlGF) and serum pregnancy associated plasma protein-A (PAPP-A). All these data will then be used for the risk calculation to determine the risk of preeclampsia using the Bayes theorem method.

At the second study visit at 19-24 weeks a routine anomaly scan will be carried out and routine data associated with this scan will be collected.

The incidence of pre-eclampsia is ascertained via data collected at 11-13 weeks gestation and 19-24 weeks gestation at routine visits and from pregnancy outcome data in patient notes collected within one month of giving birth.

Of these data, only data from all participants that developed pre-eclampsia (PE) will be analysed to test the diagnostic accuracy of both the Bayes theorem method (mini combined and combined) prediction compared to the NICE guidelines prediction (retrospectively).

The Bayes theorem combined test requires the following data: combination of maternal characteristics and medical history together with the measurements of the mean arterial pressure (MAP), uterine artery pulsatility index (PI), serum placental growth factor (PlGF) and serum pregnancy associated plasma protein-A (PAPP-A) at 11-13 weeks' gestation.

The Bayes theorem mini combined test requires the following data: A combination of maternal characteristics and medical history, MAP and PAPP-A

The NICE Guidelines for diagnosis of risk of PE requires review of the data which will be retrieved from patient notes collected at 11-13 weeks.

Intervention Type
Other

Primary outcome measure
Diagnostic accuracy (false positive and true positive frequencies) of screening for pre-eclampsia using the Bayes theorem based method is measured as the rate of pre-eclampsia, determined using medical note review within one month of birth.

Secondary outcome measures
Detection rate of pre-eclampsia is measured through medical note review within one month of birth.

Overall study start date
04/10/2015

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Singleton pregnancy
3. Live fetus at 11-13 weeks' gestation
4. Informed and written consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 16850; UK Sample Size: 16850

Total final enrolment
16747

Key exclusion criteria
1. Women who are severely ill
2. Those with learning difficulties
3. Those with a serious mental illness
4. Pregnancies complicated by major fetal abnormality identified at 11-13 weeks of gestation

Date of first enrolment
12/04/2016

Date of final enrolment
31/01/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King’s College Hospital
Harris Birthright Centre
Fetal Medicine Research Institute
16-20 Windsor Walk
London
United Kingdom
SE5 8BB

Study participating centre
Medway Maritime Hospital
Fetal Medicine Unit
Windmill Road
Gillingham
United Kingdom
ME7 5NY

Study participating centre
North Middlesex Hospital
Gynaecology, Maternity Building
Level 1
North Middlesex University Hospital NHS Trust
Sterling Way
London
United Kingdom
N18 1QX

Study participating centre
Homerton University Hospital
Fetal Medicine Unit
2nd floor Antenatal Clinic
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Southend University Hospital
Southend University Hospital NHS Foundation Trust
Kypros Nicolaides Fetal Medicine Centre
2nd Floor Cardigan Building
Prittlewell Chase
Westcliff on sea
United Kingdom
SS0 0RY

Study participating centre
University Hospital Lewisham
UItrasound Room 5
Ground Floor
Women's Health
Green Zone
Lewisham High Street
Lewisham
London
United Kingdom
SE13 6LH

Study participating centre
The Royal London Hospital
The Fetal Medicine Centre
Ward 8E, 8th floor, South Tower
Whitechapel road
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Delegated to University College London Comprehensive Clinical Trials Unit (UCL CCTU) by Kings College London

Sponsor details
Comprehensive Clinical Trials Unit
Gower Street
London
England
United Kingdom
WC1E 6BT

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in peer reviewed journals an presentation at relevant meetings.

Intention to publish date
11/07/2018

Individual participant data (IPD) sharing plan

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	01/08/2017		Yes	No
Results article	results	01/06/2018		Yes	No
HRA research summary			28/06/2023	No	No
Results article		01/11/2020	18/08/2023	Yes	No