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Prediction of preeclampsia/eclampsia in pregnant women

Submission date	Recruitment status	[ ] Prospectively registered
18/11/2015	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
20/11/2015	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/04/2022	Pregnancy and Childbirth	

Plain English summary of protocol

Background and study aims

Preeclampsia (PE) is a medical condition which can develop during pregnancy, and can affect both the mother and unborn baby. The exact cause of PE is not known, however it is thought to happen because of a problem with the placenta. The placenta is a specialised organ which connects the mother's blood supply to the baby's, providing the baby with food (nutrients) and oxygen. In PE, it is thought that the blood supply to the placenta is reduced, which can mean the unborn baby does not get enough nutrients to develop properly. It is therefore very important that the signs of PE are spotted quickly so that the mother can be treated. The early signs of PE include high blood pressure (hypertension) and the presence of protein in the urine (proteinuria), however having these symptoms does not guarantee that a woman will develop it. Currently, there is no way of testing to find out who will develop the disease, and so patients with suspected PE are admitted to hospital, often for several days in order to make the diagnosis. Over 50% of the patients admitted don't have PE, which can be a great cause of stress and anxiety to the mother, and a waste of valuable resources in the NHS. sFlt-1 and PLGF are natural chemicals produced by the placenta and released into the mother's blood. Recent studies have shown that in cases of PE, the amounts of these markers in the blood are different to normal. The aim of this study is to find out whether testing sFlt-1 and PLGF in the blood is a reliable way of predicting the chance of a woman developing PE.

Who can participate?

Adult women who are more than 24 weeks pregnant who are showing signs of PE.

What does the study involve?

Women who are showing signs of PE have a blood sample taken so that the amounts of sFlt-1 and PLGF in the blood can be measured. The women are then randomly allocated to one of two groups. For women in the first group, the result of the test is not revealed to the team looking after her, and she continues with the usual practice (being admitted to hospital and monitored). For women in the second group, the result of the test is given to the team looking after her so that they can make a decision about whether to admit her to hospital (based on the likelihood of her developing PE). If they feel that she has a low risk of developing PE, then she can be monitored as an outpatient. The accuracy of the test is then determined by seeing how many women develop PE and comparing them to the prediction from the test.

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

Where is the study run from?
Nuffield Department of Obstetrics and Gynaecology, Oxford (UK)

When is the study starting and how long is it expected to run for?
June 2015 to June 2016

Who is funding the study?
Roche Diagnostics Ltd (UK)

Who is the main contact?
Ms Georgina Longley

Contact information

Type(s)
Public

Contact name
Ms Georgina Longley

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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19292

Study information

Scientific Title

A prospective, randomised INterventional Study evaluating the short-term PredIction of pReeclampsia/Eclampsia in pregnant women with suspected preeclampsia

Acronym
INSPIRE

Study objectives
The aim of this study is to investigate whether measuring 2 placental factors (sFlt1 and PLGF) in maternal blood has the potential to predict the likelihood of preeclampsia (PE), in order to determine whether the patient requires admission or can be sent home with outpatient follow up.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford B Research Ethics Committee, 31/03/2015, ref: 15/SC/0126

Study design
Prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Reproductive Health & Childbirth; Subtopic: Reproductive Health & Childbirth; Disease: Reproductive Health & Childbirth

Interventions
Patients attending the Maternity Assessment Unit, Day Assessment Unit, Antenatal Clinics and Delivery Suite/Labour Ward with suspected preeclampsia will be approached. Consenting participants who meet the inclusion criteria have a blood sample taken at the time of which will be tested for sFlt1/PLGF. At baseline, all participants undergo baseline assessments including taking their clinical history, blood pressure (serial), urinary protein analysis (dipstick or PCR), clinical examination, assessment offetal wellbeing (CTG) and growth (clinical or ultrasound depending on clinical judgement), as well as blood sampling. The patient’s sFlt1/PLGF test result will be randomized into the “Reveal” or “Non Reveal” groups.

"Not Reveal" group: The team looking after these patients will not be given the results of the sFlt1/PLGF analysis. Participants in this group are treated according to current practices for suspected cases of preeclampsia (PE). This involves admission to hospital, blood tests, serial blood pressure measurement, and urinary protein analysis together with CTG +/- Ultrasound.

"Reveal" group: The team looking after these patients are given the results of the sFlt1/PLGF analysis. They will then use this information to decide whether the patient requires admission in conjunction with the whole clinical picture.

All patients are then reviewed one week later, where clinical history, blood pressure (serial), urinary protein analysis
(dipstick or PCR), clinical examination, assessment of fetal wellbeing (CTG) and growth (clinical or ultrasound
depending on clinical judgement) will be performed. An repeat sFlt1/PLGF test (taken under the same "reveal" or "not reveal" conditions as above i.e. no change in randomization groups) will be performed in addition to routine blood tests. Admission rates and other clinical data outlined above will be collected for both reveal and non reveal groups.

Intervention Type
Other

Primary outcome measure
Inpatient admission rate measured using electronic patient records (EPR) and case-note review at baseline, 1 week and time of delivery.

Secondary outcome measures
1. Incidence of preeclampsia is measured according to NICE guidelines at baseline, 1 week and time of delivery
2. Re-admission rate is measured using EPR at recruitment at baseline, 1 week and time of delivery
3. Birth weight is measured using EPR and casenotes at time of delivery
4. SCBU admission rate is measured using EPR at time of delivery
5. Foetal growth is measured using antenatal ultrasound scanning at baseline, 1 week and time of delivery
6. Total blood count and platelet count is measured using blood testing at baseline, 1 week and time of delivery
7. Renal and hepatic function is measured using blood testing at baseline, 1 week and time of delivery

Overall study start date
11/06/2015

Completion date
08/07/2016

Eligibility

Key inclusion criteria
1. Female aged between 18-45 years
2. Pregnant >24 weeks

3. Able to consent
4. Singleton pregnancy
5. New onset hypertension (Stratified as below – Management) AND/OR
6. New onset proteinuria AND/OR
7. New onset oedema/headache/visual Disturbance AND/OR
8. New onset hepatic/liver tenderness AND/OR epigastric pain AND/OR
9. Any other clinical suspicion of PE

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
Planned Sample Size: 366; UK Sample Size: 366

Total final enrolment
370

Key exclusion criteria
1. Unable to consent
2. Age less than 18 or over 45 at the time of recruitment
3. Unable to speak English well enough to understand the study information
4. Unwilling to participate
5. Preexisting preeclampsia
6. Multiple pregnancy or higher order pregnancy
7. Any significant disease or disorder which in the opinion of the investigator may either put the participants at risk or may influence the result of the study or the participant's ability to participate in the study

Date of first enrolment
11/06/2015

Date of final enrolment
08/06/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nuffield Department of Obstetrics and Gynaecology
University of Oxford
John Radcliffe Hospital
Headley Way
Headington
United Kingdom
OX3 9DU

Sponsor information

Organisation
Oxford University Hospitals NHS Trust

Sponsor details
Research & Development Office
Joint Research Office
Block 60
Churchill Hospital
Headington
Oxford
England
United Kingdom
OX3 7LE

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03h2bh287

Funder(s)

Funder type
Industry

Funder Name
Roche Diagnostics Ltd

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2019	14/08/2019	Yes	No
Results article		01/03/2021	22/03/2021	Yes	No
Results article	secondary analysis	14/11/2021	28/04/2022	Yes	No
HRA research summary			28/06/2023	No	No