ISRCTN82607486 https://doi.org/10.1186/ISRCTN82607486

Diagnostic accuracy in pre-eclampsia using proteinuria assessment

Submission date
15/10/2012

Recruitment status
No longer recruiting

Registration date
16/10/2012

Overall study status
Completed

Last Edited
17/12/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
We are carrying out a study of 3000 pregnant women with pre-eclampsia (high blood pressure, fluid retention and protein in the urine (proteinuria) in pregnancy) by collecting urine and comparing different diagnostic tests to find the most appropriate and effective method that predicts pre-eclampsia and its severity is needed to provide these women with the best possible care. Our aim is to find the most efficient assessment tool for diagnosing pre-eclampsia.

Who can participate?
Pregnant women, aged between 18 and 45 years of age from participating hospital trusts across England.

What does the study involved?
Participants will be invited to give a small urine sample when screened for pre-eclampsia, following 24 hour urine collection and at delivery. Woman will be asked to allow the researcher access to clinical data about them and their baby. At the end of the study the urine samples will be analysed in a laboratory using the current standard techniques for identifying pre-eclampsia.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part, but the findings from the study should benefit to future women who have suspected pre-eclampsia. This study may also help the NHS to develop more cost effective diagnosis techniques. There are no known risks to the patients taking part.

Where is the study run from?
Newcastle Upon Tyne Hospitals NHS Trust in collaboration with Newcastle University.

When is the study starting and how long is it expected to run for?
Recruitment will start beginning of November 2012 and participants will be enrolled on the study for a period of their pregnancy.

Who is funding the study?
NIHR Health Technology Programme and Newcastle University (UK)

Who is the main contact?
Dr Jason Waugh
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Contact information

Type(s)
Scientific

Contact name
Dr Jason Waugh

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6213; HTA 10/65/02

Study information

Scientific Title
Spot protein creatinine ratio (SPCr) and spot albumin creatinine ratio (SACr) in the assessment of pre-eclampsia: a diagnostic accuracy study with decision analytic model based economic evaluation and acceptability analysis

Acronym
DAPPA

Study objectives
Investigations aimed at determining which method of measurement and which diagnostic thresholds are the most accurate in predicting not just preeclampsia but the clinical significant outcomes which will help inform clinicians on the correct clinical management of gestational hypertensive disorders during pregnancy. This in turn will improve the clinicians ability predict maternal and fetal outcomes.

More details can be found here: http://www.nets.nihr.ac.uk/projects/hta/106502
Further details can be found here: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0011/81677/PRO-10-65-02.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East - County Durham & Tees Valley, 21/09/2012, ref: 12/NE/0301

Study design
Multi-centre prospective cohort observation sample collection study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
The patient information sheet is available by contacting the Chief Investigator, Jason Waugh (jason.waugh@nuth.nhs.uk)

Health condition(s) or problem(s) studied
Pre-eclampsia

Interventions
This study involves 3000 women who will provide urine samples during admission to hospital with suspected preeclampsia across England. Women will be in the study for the duration of pregnancy providing three urine samples.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Diagnostic accuracy of point of care and laboratory assessments of Spot Protein Creatine Ratio (SPCr) and Spot Albumin Creatine Ratio (SACr) compared with 24 hour urine protein measurement at different thresholds in diagnosing and predicting severe Pre-Eclampsia (PE)

Secondary outcome measures

1. To assess the accuracy of point of care assessments of SPCr and SACr at different thresholds in diagnosing PE compared to 24 hour urine protein measurement
2. To identify the most accurate laboratory assay method of 24 hour proteinuria in assessment of PE
3. To estimate the accuracy of both quantitative and point of care assessments of SPCr and SACr at different thresholds in predicting adverse fetal outcomes
4. To develop a decision analytic model to estimate the diagnostic utility potential of replacing the 24 hour protein with the SPCr or SACr
5. To assess the cost effectiveness of SPCr or SACr in comparison to the 24 hour urine protein measurement

Overall study start date
01/11/2012

Completion date
01/11/2014

Eligibility

Key inclusion criteria
1. Pregnant women aged between 16- 45 years
2. More than 20 weeks gestation with confirmed gestational hypertension (systolic BP >140 mmHg and diastolic BP >90 mmHg)
3. Trace or more proteinuria on automated dipstick urinalysis. This is below the threshold of 1+ considered "test positive" by NICE and will thus allow exploration of the lower threshold for the index tests, i.e. below 300 mg/l protein
4. Ability of give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
3000

Total final enrolment
959

Key exclusion criteria
1. Women with gestational hypertension but no proteinuria on automated dipstick urinalysis
2. Proteinuria before 20 weeks gestation
3. Pre-existing renal disease, pre-gestational diabetes and chronic hypertension
4. Those who are unable to provide informed consent
5. Those women who are already participating in a clinical trial of an investigational medicinal product (CTIMP)

Date of first enrolment
01/11/2012

Date of final enrolment
01/11/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Newcastle Upon Tyne
United Kingdom
NE1 4LP

Sponsor information

Organisation
Newcastle Hospitals NHS Foundation Trust (UK)

Sponsor details
Royal Victoria Infirmary
Joint Research Office
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/06/2017

Individual participant data (IPD) sharing plan

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	01/10/2017	17/12/2020	Yes	No