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

### Protocol serial number
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

### Primary study design
Observational

### Study design
Multi-centre prospective cohort observation sample collection study

### Study type(s)
Diagnostic

### 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(s)
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)

### Key secondary outcome(s)
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

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
Female

### 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
United Kingdom

England

### Study participating centre

**Royal Victoria Infirmary**
Newcastle Upon Tyne
United Kingdom
NE1 4LP

# Sponsor information

**Organisation**
Newcastle Hospitals NHS Foundation Trust (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, Health Technology Assessment (HTA), HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|

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|---|---|---|---|---|---|
| Results article | results | 01/10/2017 | 17/12/2020 | Yes | No |