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Diagnosis of Pulmonary Embolism in Pregnancy (DiPEP)

Submission date
01/07/2014

Recruitment status
No longer recruiting

Registration date
14/07/2014

Overall study status
Completed

Last Edited
05/09/2018

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Pulmonary embolism (PE) happens when a blood clot, usually from the veins of the legs, breaks off and travels to the lungs. A large clot can cause shortness of breath, chest pain and fainting. In extreme cases, it can cause severe heart and lung damage and even death. Death in pregnancy is very rare, but PE is one of the commonest causes when it happens. The typical symptoms of PE (chest pain or shortness of breath) are common in pregnancy and are not usually cause for alarm. We estimate that only one in every 50 women investigated for suspected PE actually has the condition. Tests for PE are not without risk. Scans used to diagnose the condition use radiation that may slightly increase the risk of cancer in the mother and cause harm to the unborn baby. Furthermore, all tests carry the risk of a false positive result in which a harmless abnormality is incorrectly diagnosed as being a blood clot. In these cases, women can be given unnecessary treatment to thin the blood, which can cause serious bleeding in a small number of people. The number of women that are tested for PE and then found not to have it is quite high, and shows how keen health professionals are to not miss this potentially fatal condition. However, these tests could be causing harm to perfectly healthy expectant mothers and their babies. Clinical prediction rules, in which researchers try to work out which combination of symptoms and other medical findings are most likely to be caused by a particular medical condition, have been used to identify which non-pregnant patients that are showing symptoms of PE need further investigation. These, however, have not been properly tested in pregnant women. The small number of pregnant women with suspected PE that are then diagnosed with the condition makes it very difficult to do this. We estimate that, for such a study, we would need 6000 women across 50 hospitals over 6 years at a cost of £6million, with no guarantee of a reliable result. We are therefore trying a different approach, testing ways of selecting pregnant and postpartum women (women who have just given birth) that may have PE for further investigation. Our study will also test whether there are enough eligible women willing to take part in the research to make further study worthwhile.

Who can participate?
1. Pregnant and postpartum women with diagnosed or suspected PE from all UK hospitals.
2. Pregnant and postpartum women with suspected PE or diagnosed deep vein thrombosis (a blood clot in the vein which may then cause a PE) from 8 hospitals over 18 months

What does the study involve?
Data will be collected over the next 18 months from all UK hospitals from women who either may have the condition, or have actually been diagnosed. Using this data, we are going to test both existing clinical prediction rules, rules that have been improved and new rules to see which correctly predicts which women had PE. We are also collecting blood from pregnant women with deep vein thrombosis to see whether blood tests can accurately identity clots. A mathematical model will be developed, which will weigh up the benefits of diagnosing and treating PE against the risks and the costs involved. This model will then be used to compare different ways of testing for PE and decide which one is best. It will also explore whether the cost of further research is justified given the smaller number of women that have to be tested for PE.

What are the possible benefits and risks of participating?
There are no significant risks or benefits associated with taking part. Some women will be asked to provide a small additional amount of blood when a sample is taken for diagnostic testing.

Where is the study run from?
Sheffield Teaching Hospital NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
October 2014 to March 2015

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

Who is the main contact?
Prof Steve Goodacre
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Study website
http://www.sheffield.ac.uk/scharr/sections/dts/ctru/dipep

Contact information

Type(s)
Scientific

Contact name
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Regent Court
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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/21/01

Study information

Scientific Title
Diagnosis of pulmonary embolism in pregnancy: a case-control study, biomarker study and decision-analysis modelling of effectiveness, cost-effectiveness and value of information

Acronym
DiPEP

Study objectives
This study aims to:
1. Estimate the diagnostic accuracy, effectiveness and cost-effectiveness of strategies (including clinical prediction rules) for selecting pregnant or postpartum women with suspected PE for imaging
2. Determine the feasibility and value of information of further prospective research

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/132101
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/123363/PRO-13-21-01.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - Brent, 10/10/2014, REC ref: 14/LO/1695

Study design
Case-control study, biomarker study and decision-analysis modelling of effectiveness, cost-effectiveness and value of information

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Not provided at time of registration

Health condition(s) or problem(s) studied
Pulmonary embolism in pregnancy

Interventions
The study will be testing clinical predictors and biomarkers for PE, and diagnostic strategies (including clinical prediction rules) used to select pregnant or postpartum women for imaging. Data will be collected in hospital up to the point at which women have diagnostic imaging and then by hospital record review and email/telephone/mail contact at 30 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pulmonary embolism (PE)
2. Cost-effectiveness
The outcome for diagnostic accuracy (case-control) study will be diagnosis of PE based on diagnostic imaging and any adverse events up to 30 days. The outcome for the cost-effectiveness analysis will be life-time quality-adjusted life years (QALYs), estimated by decision analysis modelling.

Secondary outcome measures
None

Overall study start date
01/10/2014

Completion date
31/03/2017

Eligibility

Key inclusion criteria
1. Pregnant and postpartum women with diagnosed PE from all UK hospitals over 18 months
2. Pregnant and postpartum women with suspected PE or diagnosed DVT from 8 hospitals over 18 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
150 women with diagnosed PE, 250 with suspected PE and 20 with diagnosed DVT

Key exclusion criteria
1. Women who did not present with suspected PE
2. Women who are unable to consent, requiring resuscitation or with an existing diagnosis of PE

Date of first enrolment
01/10/2014

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Regent Court
Sheffield
United Kingdom
S1 4DA

Sponsor information

Organisation
Sheffield Teaching Hospital NHS Foundation Trust (UK)

Sponsor details
c/o Erica Wallis
Sheffield
England
United Kingdom
S10 2SE

Sponsor type
Hospital/treatment centre

ROR

https://ror.org/018hjpz25

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

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

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?
Results article	results	01/03/2018		Yes	No
Basic results		21/06/2018	21/06/2018	No	No
Results article	results	01/08/2018		Yes	No
Results article	results	01/02/2019		Yes	No
HRA research summary			28/06/2023	No	No