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A randomised trial comparing four methods of investigating patients with suspected pulmonary thrombo-embolism

Submission date 25/04/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 25/04/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/05/2016	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 96/07/03

Study information

Scientific Title
A randomised trial comparing four methods of investigating patients with suspected pulmonary thrombo-embolism

Study objectives
Diagnosis of pulmonary thrombo-embolus is problematic and there have been recent calls for a change in diagnostic strategy.
We intend to investigate the diagnostic effectiveness and cost effectiveness, by studying confidence of diagnosis, and the cost benefit, by studying three month outcome measures (recurrence, complications of treatment, morbidity and mortality), of four imaging protocols in patients suspected of pulmonary thrombo-embolus randomised to these protocols. Results will provide data regarding efficient diagnostic stratagems guiding cost-effective patient management and influencing future capital expenditure.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Cardiovascular diseases: Thromboembolic disease

Interventions
A randomised, open clinical trial in a single centre of four investigational protocols: patients are randomised into one of the protocols.
1. V/Q scan +/- lower limb doppler ultrasound +/- clinical assessment of risk
2. V/Q scan +/- lower limb doppler ultrasound +/- conventional pulmonary angiography

3. Contrast enhanced volumetric Computed Tomography (CT) +/- lower limb doppler ultrasound
4. Pulmonary and lower limb Magnetic Resonance Imaging (MRI)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Follow-up will monitor: Days in hospital. Other investigations. Treatment costs. Recurrent thrombo-embolic disease in three months following investigation. Readmission and subsequent costs.

Secondary outcome measures
Not provided at time of registration.

Overall study start date
01/04/1999

Completion date
31/03/2002

Eligibility

Key inclusion criteria
Patients suspected of acute pulmonary embolus normally investigated with ventilation-perfusion (V/Q) radionucleide scanning. 18 years or greater. Giving informed consent.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration.

Key exclusion criteria
Unable to give informed consent. Pregnant. Contraindication to any one of the above protocols.

Date of first enrolment
01/04/1999

Date of final enrolment
31/03/2002

Locations

Countries of recruitment
Canada

United Kingdom

Study participating centre
Department of Medical Imaging
Ontario
Canada
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Sponsor information

Organisation
Department of Health (UK)

Sponsor details
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Sponsor type
Government

Website
http://www.dh.gov.uk/en/index.htm

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration