

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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration.

Completion date

31/03/2002

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

United Kingdom

Canada

Study participating centre

Department of Medical Imaging

Ontario

Canada

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Sponsor information

Organisation

Department of Health (UK)

ROR

<https://ror.org/03sbpja79>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration