

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

Submission date 25/04/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/04/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 24/05/2016	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Alan Moody

Contact details

Department of Medical Imaging
Sunnybrook & Women's Health Sciences Centre, Ontario
2075 Bayview Avenue
Toronto
Ontario
Canada
M4N 3M5

-
alan.moody@sunnybrook.ca

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) radionuclide 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

M4N 3M5

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Quarry House

Quarry Hill

Leeds

United Kingdom

LS2 7UE

+44 (0)1132 545 843

Sheila.Greener@doh.gsi.gov.uk

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