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Pulmonary embolism diagnosis study

Submission date 26/09/2005	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 26/09/2005	**Overall study status** Completed	
Last Edited 21/04/2008	**Condition category** Circulatory System	

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
MCT-44150

Study information

Scientific Title

Study objectives
We hypothesise that relying on the use of spiral Computed Tomography (CT) as opposed to V/Q scanning as the initial pulmonary imaging procedure to exclude the diagnosis of PE will result in similar rates of subsequent venous thromboembolic events and will be cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Queen Elizabeth II Health Sciences Centre Research Ethics Committee on the 8th March 2001.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pulmonary embolism (PE)

Interventions
Clinical model to identify PE likely or unlikely, Ddimer blood test, randomised to receive either V /Q or CT for diagnosis of possible PE, in majority of cases would have ultrasound to rule out deep vein thrombosis.

Trial details received: 12 September 2005

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Symptomatic venous thromboembolism.

Secondary outcome measures
1. Asymptomatic venous thromboembolism
2. Death
3. Bleed (major and minor)

Overall study start date
01/11/2005

Completion date
31/07/2006

Eligibility

Key inclusion criteria
Consecutive adult patients (18 years and older) of either sex, presenting with symptoms or signs suspected by a physician of being caused by acute pulmonary embolism (acute onset of new or worsening shortness of breath, chest pain, hemoptysis, presyncope or syncope) will be potentially eligible for this study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1530

Key exclusion criteria
1. Deep vein thrombosis or pulmonary embolism within the previous 3 months
2. No worsening of the severity of pulmonary symptoms within the previous 2 weeks
3. Use of therapeutic doses of parenteral anticoagulants for greater than 48 hours
4. Co-morbid condition making life expectancy less than 3 months
5. Contradiction to contrast media
6. A need for long-term use of anticoagulants
7. Pregnancy
8. Age less than 18 years
9. Refusal to give informed consent
10. Geographic inaccessibility to follow-up

Date of first enrolment

01/11/2005

Date of final enrolment
31/07/2006

Locations

Countries of recruitment
Canada

Study participating centre
Queen Elizabeth II Health Science Centre
Halifax
Canada
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Sponsor information

Organisation
Queen Elizabeth II Health Science Centre (Nova Scotia) (Canada)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/025qrzc85

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-44150)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	19/12/2007		Yes	No