

Pulmonary embolism diagnosis study

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|--|---|---|
| Submission date 26/09/2005 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 26/09/2005 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 21/04/2008 | Condition category Circulatory System | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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

B3H 2Y9

Sponsor information

Organisation

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

Sponsor details

1278 Tower Road

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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 |