Simple and safe exclusion of pulmonary embolism using quantitative d-dimer and Wells simplified decision rule

Submission date	Recruitment status No longer recruiting	Prospectively registered		
22/11/2006		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/11/2006	Completed	[X] Results		
Last Edited 03/11/2008	Condition category Circulatory System	[] 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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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR757

Study information

Scientific Title

Study objectives

Excluding pulmonary embolism (PE) by a clinical decision rule (CDR) indicating PE unlikely, assessed by the Wells simplified decision rule, combined with a normal D-dimer is safe and efficient.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Multicentre, randomised, two-armed clinical 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, clinically suspected

Interventions

Upon clinical suspicion, Wells clinical decision rule was performed first and if patients had a score of less than 4.0 points, a D-dimer test followed. Patients with a normal D-dimer concentration had no further tests, pulmonary embolism was considered excluded and patients did not receive anticoagulant treatment.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Patients, in whom pulmonary embolism was excluded, were followed up for three months to document the occurrence of venous thromboembolic events or death.

Secondary outcome measures

No secondary outcome measures

Overall study start date

01/03/2002

Completion date

01/06/2004

Eligibility

Key inclusion criteria

Outpatients with clinically suspected PE

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

879

Key exclusion criteria

- 1. Anticoagulant therapy for more than 24 hours
- 2. Aged under 18 years
- 3. Pregnancy
- 4. Allergy to contrast media
- 5. Expected survival less than three months
- 6. Venous thrombo-embolism in the previous six months
- 7. Refusal or inability to consent

Date of first enrolment

01/03/2002

Date of final enrolment

01/06/2004

Locations

Countries of recruitment

Netherlands

Study participating centre Leiden University Medical Hospital

Leiden Netherlands 2300 RC

Sponsor information

Organisation

Leiden University Medical Centre (LUMC) (The Netherlands)

Sponsor details

Department of General Internal Medicine P.O. Box 9600 Leiden Netherlands 2300 RC

Sponsor type

Hospital/treatment centre

Website

http://www.lumc.nl/english/start_english.html

ROR

https://ror.org/027bh9e22

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Unrestricted grants from the participating hospitals

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 summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	01/01/2007		Yes	No