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

Submission date 22/11/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/11/2006	**Overall study status** Completed	
Last Edited 03/11/2008	**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
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
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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 summary

Not 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