

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/11/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 03/11/2008	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

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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/06/2004

Eligibility**Key inclusion criteria**

Outpatients with clinically suspected PE

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/027bh9e22>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Unrestricted grants from the participating hospitals

Results and Publications

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