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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25993

Source
NTR

Brief title
N/A

Health condition

Clinically suspected pulmonary embolism.

Sponsors and support

Primary sponsor: N/A
Source(s) of monetary or material Support: unrestricted grants from the participating hospitals

Intervention

Outcome measures

Primary outcome

Patients, in whom pulmonary embolism was excluded, were followed up for 3 months to document the occurrence of venous thromboembolic events or death.

Secondary outcome

N/A

Study description

Background summary

In conclusion, this large study has prospectively demonstrated the safety of excluding pulmonary embolism by the use of a dichotomous clinical decision rule and D-dimer test in patients with suspected pulmonary embolism. We have established that by implying such a non-invasive strategy anticoagulant therapy can safely be withheld with great efficiency involving more than 50 % of patients, thus obviating the need for more invasive and costly tests, including CT scan and perfusion lung scan. The standard approach in the diagnostic management of PE should now be to start with a clinical decision rule and a quantitative D-dimer test and rely on the outcome of these two tests. If the clinical decision rule indicates PE to be likely present or if the D-dimer test is abnormal, further imaging tests are warranted.

Study objective

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

Study design

N/A

Intervention

Upon clinical suspicion, Wells clinical decision rule was performed first and if patients had a score of 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.

Contacts

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Eligibility criteria

Inclusion criteria

Outpatients with clinically suspected PE.

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 3 months;

6. venous thromboembolism in the previous 6 months;

7. refusal or inability to consent.

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2002
Enrollment:	879
Type:	Actual

Ethics review

Positive opinion

Date:	30-08-2006
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL747
NTR-old	NTR757
Other	: N/A
ISRCTN	ISRCTN10533382

Study results

Summary results
Thromb Haemost. 2007 Jan;97(1):146-50.