A simplified diagnostic algorithm for suspected pulmonary embolism

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29438

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Diagnostic algorithm / diagnostisch algoritme
Pulmonary embolism / longembolie

Sponsors and support

Primary sponsor: Leiden University Medical Center
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

(recurrent) PE, DVT

Secondary outcome

mortality, number of performed CTPA.

Study description

Background summary

Rationale: Current diagnostic algorithms for pulmonary embolism (PE) still result in a high number of negative computed tomography pulmonary angiography (CTPA) scans. In addition, they are relatively complex resulting in low application in clinical practice outside clinical studies. Recently, a post-hoc study demonstrated a safe, simplified and more efficient diagnostic strategy. With this registry, we aim to evaluate this strategy prospectively.

Objectives: 1) to evaluate the clinical utility and safety of the YEARS algorithm; 2) to assess the percentage of patients in whom a CTPA was required.

Design: A prospective multi-center registry of consecutive patients with suspected (recurrent) PE. Participants will be evaluated according to the YEARS algorithm consisting of three items of the original Wells rule (clinical signs of DVT, hemoptysis, 'PE most likely diagnosis') and a D-dimer test. In patients without any of the three items and a D-dimer level <1.0 µg/mL, and in patients with ≥1 items and a D-dimer level <0.5 µg/mL a PE is excluded without CTPA. In the other patients a CTPA will be performed. All patients will be followed for a period of 3 months.

Study objective

To evaluate the safety and efficiency of a new diagnostic strategy for patients with suspected pulmonary embolism

Study design

Follow-up duration: the primary and secondary endpoints will be determined after 3 months follow-up.

Intervention

A prospective multi-center management registration of consecutive patients with suspected (recurrent) PE. Participants will be evaluated according to the YEARS algorithm consisting of three items of the original Wells rule (clinical signs of DVT, hemoptysis, 'PE most likely diagnosis') and a D-dimer test. In patients without any of the three items and a D-dimer level <1.0 µg/mL, and in patients with ≥1 items and a D-dimer level <0.5 µg/mL a PE is excluded

without CTPA. In the other patients a CTPA will be performed. All patients will be followed for a period of 3 months.

Contacts

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Eligibility criteria

Inclusion criteria

Consecutive patients with suspected (recurrent) PE.

Exclusion criteria

-life expectancy <3 months

- treatment with full-dose therapeutic low molecular weight heparin or unfractionated heparin that was initiated 24 hours or more prior to eligibility assessment

- treatment with vitamin K antagonists (coumarin derivates)

- contraindication to helical CT.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	07-10-2013
Enrollment:	3260
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-10-2013
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	NL4020
NTR-old	NTR4193
Other	: P13.151
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A