

Prometheus-Study: Diagnostics

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Evaluation of four clinical decision rules to exclude a pulmonary embolism (Wells rule, revised Geneva score, simplified Wells rule and the simplified revised Geneva score). Evaluation if it is safe and easy to use this rules. Beside this, the...

Ethical review	-
Status	Pending
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON31601

Source

ToetsingOnline

Brief title

Prometheus-Diagnostics

Condition

- Embolism and thrombosis

Synonym

pulmonary embolism, venous tromboembolism

Research involving

Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clinical decision rules, Diagnostics, Pulmonary embolism

Outcome measures

Primary outcome

(Recurrent) pulmonary embolism or a deep vein thrombosis during three months follow-up in the groups of patients in which a pulmonary embolism is excluded by the clinical decision rules and D-dimer or by CT scan.

Secondary outcome

Not applicable

Study description

Background summary

A combination of different tests is used to diagnose or exclude a pulmonary embolism. The clinical decision rule (according to Wells), a D-dimer and a CT-scan. The usefulness of this combination is approved in other studies with patients with a suspicion of a first pulmonary embolism. Another rule is developed (the revised Geneva score) and a simplified version is made of both rules (the Wells and revised Geneva score), in which each item gets only one point. It is possible that with one of this new rules it is safer or easier to exclude a pulmonary embolism than happens until now. And maybe less CT-scans are necessary in the future. It is uncertain if the standard combination of tests can safely exclude a recurrent pulmonary embolism.

Study objective

Evaluation of four clinical decision rules to exclude a pulmonary embolism (Wells rule, revised Geneva score, simplified Wells rule and the simplified revised Geneva score). Evaluation if it is safe and easy to use this rules. Beside this, the clinical decision rule according to Wells is evaluated in patients with a suspected recurrent pulmonary embolism, if it is safe to withholding treatment with anticoagulants in case of exclusion of a pulmonary embolism.

Study design

Prospective multi- centre cohort study

Twelve hospitals are participating.

Study burden and risks

During the diagnostic process, one additional tube of blood is obtained to test for factors that may be of influence on the development or the diagnostic process of a pulmonary embolism, it is not a DNA test.

In the group of patients in which the clinical decision rules disagree, an additional CT scan is performed. This would not be a standard procedure without this study. Because of this study, 23% additional scans are performed. The effective dose of a single CT varies between 2.8 and 3.9 mSV. The risks of this additional radiation depends on the age of the patient.

Beside this two tests, a patient is called after three months with the question if in the meanwhile a pulmonary embolism or a deep vein thrombosis developed. This phone call takes 5 minutes of time.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with clinically suspected pulmonary embolism

Exclusion criteria

Age < 18 Years

LMWH or unfractionated heparin 24 hours or more prior to eligibility assesment

Vitamin K antagonists (coumarin derivates)

Allergy to intravenous iodinated contrast

Renal insufficiency (estimated creatinine clearance < 30 ml/min)

Preagnancy

Life expectancy < 3 months

Impossibility to return for follow-up

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-02-2008

Enrollment: 800

Type: Anticipated

Ethics review

Approved WMO

Date: 04-09-2009

Application type: Amendment

Review commission: METC Leids Universitair Medisch Centrum (Leiden)

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
CCMO	NL21228.058.07