Prometheus-Study: Follow-up

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To assess the extent of pulmonary thrombo-embolic obstruction and cardiopulmonary function at presentation and after 6 months of anticoagulant treatment in patients with an acute pulmonary embolism. To assess risk factors for persistent obstruction...

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

Summary

ID

NL-OMON31869

Source
ToetsingOnline

Brief title
Prometheus-Follow-up

Condition

- Embolism and thrombosis

Synonym
pulmonary embolism, venous thrombosis

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: D-dimer, Follow-up, Pulmonary embolism, Residual embolism

Outcome measures

Primary outcome

Pulmonary thrombo-embolic obstruction after 6 months of treatment,

cardiopulmonary function (incidence of chronic thrombo-embolic hypertension),

recurrent pulmonary embolism.

Secondary outcome

Not applicable

Study description

Background summary

In a systematic review, it was shows that more than 50% of all patients with a pulmonary embolism have incomplete resolution of the embolism, 6 months after diagnosis. The studies differed largely in patient selection, duration of treatment, imaging test and timing of follow-up scan.
It is currently not very well known which patients will get recurrent pulmonary embolism and chronic thrombo-embolic hypertension and the reason they develop these complications
An increased D-dimer level after stopping anticoagulant treatment was associated with increased risk of recurrence in patients with deep vein thrombosis. It is unknown how D-dimer levels behave during treatment. ideally, levels of blood coagulation activation, measured during treatment, could simplify decisions for duration of treatment.

Study objective

To assess the extent of pulmonary thrombo-embolic obstruction and cardiopulmonary function at presentation and after 6 months of anticoagulant treatment in patients with an acute pulmonary embolism. To assess risk factors for persistent obstruction and/or recurrent pulmonary embolism or deep vein thrombosis. And assess the incidence of recurrent pulmonary embolism and chronic thrombo-embolic hypertension.

Study design

A prospective multi-center cohort study.

Twelve hospitals are participating in this study.

Study burden and risks

A second CT-scan is performed after 6 months of anticoagulant treatment. The effective radiation dose of a single CT scan varies between 2.8 and 3.9 mSV, and this constitutes the amount of additional radiation as a consequence of this study. Risk of this additional radiation depends on the age of the patient.
At the same as the CT-scan an appointment is made for blood sampling and two questionnaires.
One month after the second scan, a visit is planned for control and blood sampling.
After this a half yearly follow-up is planned, this will be done by an interview by telephone about quality of life and cardio-pulmonary function.

Contacts

Public
Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
NL
Scientific
Leids Universitair Medisch Centrum

Postbus 9600
2300 RC Leiden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with a pulmonary embolism, diagnosed by helical computed tomography (CT)

Exclusion criteria

Age < 18 years
Pregnancy
Impossibility to return for follow-up
Inserted vena cava filter or thrombolytic therapy
Allergy to intravenous iodinated contrast
Renal insufficiency (estimated creatinine clearance < 30 ml/min)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2008
Enrollment:	460
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	NL21243.058.07