Athero-thrombosis risk in patients with venous thrombo-embolism

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Primary objective:To determine the individual cardiovascular risk profile, using validated risk score screening methodologies (Framingham, PROCAM, Reynolds Risk Score and SCORE) in patients with VTE to evaluate how many patients are at risk for...

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

Summary

ID

NL-OMON34860

Source
ToetsingOnline

Brief title
ATRISK Study

Condition

- Embolism and thrombosis

Synonym
cardiovascular disease, venous thrombo-embolism

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: athero-thrombosis, cardiovascular disease, Pulmonary embolism, venous thrombo-embolism

Outcome measures

Primary outcome

The proportion of VTE patients who are at risk for future cardiovascular

events.

Secondary outcome

- The proportion of VTE patients who have an increased risk of cardiovascular

disease that was not previously recognized.

- The frequency of an unfavourable cardiovascular risk profile in patients with

an unprovoked VTE compared to those with provoked VTE.

Study description

Background summary

Recently there has been a lot of interest in a possible link between venous and arterial thrombosis. The association has been extensively studied in case-control and cohort studies of both retrospective and prospective design. In individuals with venous thrombo-embolism (VTE), a high risk of subsequent (fatal and nonfatal) arterial thrombotic events has been observed. An association between endothelial dysfunction and increased intima media thickness, both signs of early, preclinical atherosclerosis and VTE has also been shown, especially in unprovoked VTE. All this evidence has led to the assumption that individuals who have suffered from VTE have a higher risk of subsequent arterial thrombosis. We therefore propose a study in which VTE patients are screened for cardiovascular risk factors. The number of patients with VTE and an elevated risk score determined by a validated risk assessment tool (SCORE) for cardiovascular disease will be assessed.

Study objective

Primary objective:

To determine the individual cardiovascular risk profile, using validated risk score screening methodologies (Framingham, PROCAM, Reynolds Risk Score and SCORE) in patients with VTE to evaluate how many patients are at risk for future cardiovascular events and will potentially benefit from cardiovascular prevention.

Secundary objectives:

- To determine in how many patients an increased risk of cardiovascular disease was previously unrecognized.
- To determine whether patients with unprovoked VTE more frequently have an unfavorable cardiovascular risk profile compared to those with provoked VTE.

Study design

In this multi-centered prospective cohort study, patients between 40 and 79 years of age presenting with a first or recurrent episode of deep vein thrombosis or pulmonary embolism will be recruited from the Department of Vascular Medicine of the Academic Medical Centre in Amsterdam and of the Slotervaart Hospital in Amsterdam. During the routine outpatient clinic check up visit three to six months after the VTE, analysis of the risk of cardiovascular events will be performed. A clinical history will be obtained from all patients regarding family history of cardiovascular disease, smoking, co-morbidity and medication. Measurements of blood pressure (three times), waist hip ratio (WHR), and BMI will take place during this visit. Blood will be drawn for blood glucose levels, HbA1c, lipid profile (levels of total cholesterol, HDL-c, LDL-c, and triglycerides), renal function (serum creatinine) and hsCRP. A urine sample will be analysed for urine albumine and creatinine. Furthermore an electrocardiogram will be made for all patients. The ten-year risk of fatal and non-fatal cardiovascular events for each patient will be determined using risk score screening methodologies (Framingham, PROCAM, Reynolds Risk Score and SCORE).

Study burden and risks

The burden and risk associated with participation are minimal. Participants will be asked to visit our studycentre on a single occasion for 30 minutes. Since bloodsampling will be performed in a fasting state, participants will have to refrain from eating and drinking prior to their visit. The only risk for the subjects is a hematoma as a result of the venapuncture. The participants can gain personal benefit from the study since analysis of their cardiovascular risk is performed and associated medical advice is given.

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

All consecutive patients between 40 and 79 years old who previously presented themselves at the Slotervaart hospital in Amsterdam and the Academic Medical Centre in Amsterdam with an objectified first or recurrent episode of deep vein thrombosis or pulmonary embolism will be included.

Exclusion criteria

All patients younger than 40 years and older than 79 years of age will be excluded.

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):	01-02-2010
Enrollment:	161
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL30998.018.10