HDL profiling in patients with deep vein thrombosis

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Does a deep vein thrombosis coincide with changes in HDL protein composition? What are the effects of anticoagulant therapy on HDL protein composition during therapy and after discontinuation of therapy?

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON34805

Source
ToetsingOnline

Brief title
The PROFILE study

Condition

- Other condition
- Embolism and thrombosis

Synonym
trombose, venous thrombo-embolism

Health condition

lipiden

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Deep vein thrombosis, HDL protein composition, protein profiling

Outcome measures

Primary outcome

Protein profiling of HDL will be done using SELDI-TOF mass spectrometry.

Additional laboratory testing will include determination of lipid spectrum (HDL-c, LDL-c, triglycerides, apo A1, apoB, total cholesterol), measurements of coagulation markers (aPTT, PT, protein S, activated protein C, F1+2, factor VIII, vWF), markers of fibrinolysis (ddimer) and inflammatory markers (CRP, Il-6, TNF-a, MCP, Leucocytes, SAA).

Secondary outcome

Additional laboratory testing will include determination of lipid spectrum (HDL-c, LDL-c, triglycerides, apo A1, apoB, total cholesterol), measurements of coagulation markers (aPTT, PT, protein S, activated protein C, F1+2, factor VIII, vWF), markers of fibrinolysis (ddimer) and inflammatory markers (CRP, Il-6, TNF-a, MCP, Leucocytes, SAA).

Study description

Background summary

In spite of significant developments and insights in the pathophysiology of athero-thrombotic disease, cardiovascular disease is still one of the most important causes of death in the western world. Medication to lower LDL

cholesterol, one of the major risk factors for atherosclerotic disease, has not reduced morbidity and mortality due to CVD. Researchers now aim to explore the influence of other possible determinants of CVD risk, like HDL cholesterol. Studies show altered protein compositions of HDL particles, against an inflammatory background, which may eventually lead to a pro-atherogenic state. Data on an association between arterial and venous disease is accumulating, and common risk factors have been identified, suggesting common pathways. Limited data suggests dyslipidemia may be associated with venous thrombo-embolic disease too. Risk of recurrent DVT has been shown to be associated with both low HDL levels and low levels of large HDL particles. We aim to analyse the association between deep vein thrombosis and HDL protein composition.

Study objective

Does a deep vein thrombosis coincide with changes in HDL protein composition? What are the effects of anticoagulant therapy on HDL protein composition during therapy and after discontinuation of therapy?

Study design

Patients will be recruited from the Department of Vascular Medicine of the Academic Medical Centre in Amsterdam. 10 consecutive patients presenting with a DVT will be included. Serial protein profiling of HDL will be done using SELDI-TOF mass spectrometry on three different time points (at baseline, 3 to 6 months after initiation of anti-coagulant therapy and one month after discontinuation of anti-coagulant therapy) and will take place during routine hospital visits, with the exception of one additional study visit. Patients (age and sex-matched) with complaints of the leg in whom a DVT has been excluded will serve as controls and will undergo blood sampling at the same time points as the cases.

Study burden and risks

Venapuncture will be the only invasive procedure and will be performed on three occasions. A total of 75 ml of blood will be drawn (25 ml during each visit). Since the first and second time points will be combined with a routine hospital visit, only the third hospital visit will be additional. Furthermore during the second and third visit, fasting blood samples will be taken for the purpose of this study (not related to routine patient care). Participants will be compensated for any travelling expenses.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Cases: All patients with a first episode of a (objectified) deep vein thrombosis aged 18 years and older are eligible for participation.
Controls: Age and sex-matched individuals with complaints of the leg, in whom a DVT has been exluded by means of ultrasonography.

Exclusion criteria

Those patienten with a previous venous thrombo-embolism, malignancy or other medical indication requiring long term anticoagulant treatment. Furthermore those patients with a history of cardiovascular disease or those using lipid lowering medication are not eligible for participation.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	20
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	NL30474.018.09