Venous Malformation and Coagulation

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To identify the abnormalities in the coagulation system leading to VTE and other thrombotic complications and to determine the prevalence of subclinical and clinically manifest thrombophlebitis and/or DVT in a well-defined Dutch VM population.

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

Summary

ID

NL-OMON32975

Source
ToetsingOnline

Brief title
VM and Coagulation

Condition

- Embolism and thrombosis

Synonym
deep vein thrombosis, venous malformation, venous thromboembolism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: coagulatioin, thrombosis, venousmalformations, venousthromboembolism

Outcome measures

Primary outcome

1.) Signs of superficial or deep vein thrombosis on compression ultrasonography

of the limbs; 2.) Measurement of blood coagulation parameters.

Secondary outcome

na

Study description

Background summary

Patients with venous malformations may have localized intravascular coagulopathy (LIC), characterized by elevated D-dimer levels, and causing (painful) thrombosis and palpable phlebolith formation. At the same time, fibrin levels may be low, causing a higher bleeding risk. It is conceivable that an activated coagulation state could lead to potential thrombotic complications such as superficial or deep vein thrombosis, pulmonary embolism (PE) or chronic thromboembolic pulmonary hypertension (CTEPH). Currently, the prevalence of venous thromboembolism in patients with venous malformations is unknown. A better insight in the frequency of thrombotic complications and coagulation abnormalities may in the future help to select those patients who need anticoagulant therapy, either in prophylactic or therapeutic dosages.

Study objective

To identify the abnormalities in the coagulation system leading to VTE and other thrombotic complications and to determine the prevalence of subclinical and clinically manifest thrombophlebitis and/or DVT in a well-defined Dutch VM population.

Study design

Cross-sectional observational study.

Study burden and risks

This research aims no direct therapeutic effects for the participants. However, the benefits are improved diagnostic possibilities and a better insight in the

pathophysiology and natural history. A better insight in the frequency of thrombotic complications and coagulation abnormalities may in the future help to select those patients who need anticoagulant therapy, either in prophylactic or therapeutic dosages. We guarantee low risk assessment because the investigations are very limited for patients and will be performed by experienced investigators.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged * 12 years with a venous malformation.

Exclusion criteria

-Patients with a vascular malformation other than a pure venous malformation
-Patients who refuse informed consent.
-Vascular malformation with a maximum surface smaller than 4 cm2 with an estimated extent in depth less than 4 cm.

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):	01-04-2009
Enrollment:	100
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	NL27241.018.09