Het ontstaan van post trombotisch syndroom.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25244

Source
Nationaal Trial Register

Brief title
If PTS

Health condition

Post thrombotic syndrome
Deep venous thrombosis

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
Source(s) of monetary or material Support: European union

Intervention

Outcome measures

Primary outcome

The primary outcome will be the difference in levels of plasma concentrations of markers in relation to the outcome PTS between patients with PTS and patients without PTS.

Secondary outcome

1. Dose-dependent relation between the level of markers and severity of PTS;

2. Plasma concentration of markers in healthy controls that never had a DVT, compared to patients that have had a DVT.

Study description

Background summary

Background:

Post thrombotic syndrome (PTS) is a chronic complication of deep venous thrombosis, associated with a decreased quality of life and at the same time posing a significant economic burden to society. Up until now the pathogenesis of PTS is not fully understood. Inflammation and fibrosis are thought to be the key players in the pathogenesis of this condition. Innate immunity may determine thrombus resolution and therefore influence the risk of PTS. Markers of inflammation, but also markers for fibrosis or fibrinolysis, may be of use to unravel the pathogenic processes involved in post thrombotic changes to the vessel wall. Finding associations between these markers and PTS can therefore help us to extend the knowledge on the pathogenesis of PTS.

Objective:

To investigate the role of innate immunity and fibrinolysis in developing PTS by studying the association between markers of immunity, fibrosis and fibrinolysis.

Study design:

Observational hypothesis generating study that is performed as a case-control study.

Study population:

The cases are a group of 30 patients who had a DVT 2-10 years ago and consequently developed PTS. The controls are a group of 30 patients who had a DVT 2-10 years ago, but did not develop PTS. The controls are matched on age, gender and BMI.

A second control group consists of healthy controls, 30 healthy people who have never had a DVT during their life. The patients will be recruited from the Maastricht University Medical

Centre and the Flevohospital in Almere. As healthy controls partners, brothers, sisters, other relatives or friends of the patients will be asked.

Intervention:

The participants will be asked to visit the hospital once-only for 3 tubes of blood to be drawn.

Study parameters:

The plasma levels of a panel of markers in participants with PTS compared to participants without PTS.

Risks:

The risks for all subjects participating in this study are the risks of a normal venipuncture: hematoma or continued bleed at the place of puncture.

Study objective

The markers CRP, D-dimer, Il-6, MCP-1, IFN-alfa, TLR-9, TGF-beta, MMP-2 or MMP-9 measured at least 2 year after the acute event of DVT are associated with PTS.

Study design

N/A

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Cases:

1. Minimum age 18 years;

2. Consenting;

3. Having had a DVT 2-10 years ago;

4. PTS according to the Villalta scale: Villalta score ¡Ý5 on two or more consecutive visits that were at least 3 months apart or venous ulceration.

Controls:

1. Minimum age 18 years;

2. Consenting;

3. Having had a DVT 2-10 years ago;

4. No PTS, according to the Villalta scale: No Villalta score ¡Ý5 on two or more consecutive visits that were at least 3 months apart and no venous ulceration.

Healthy controls:

1. Minimum age 18 years;

2. Consenting;

3. Never had a DVT during their life;

4. No venous insufficiency caused by other factors (CEAP<3).

Exclusion criteria

Pre-existent venous insufficiency (skin signs C3-C6 on CEAP score or requiring ECS therapy).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2011
Enrollment:	90
Type:	Actual

Ethics review

Positive opinion

Date:	14-11-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35458
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2993
NTR-old	NTR3141
CCMO	NL38236.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35458

Study results

Summary results
Bouman AC, Cheung YW, Spronk HM, Schalkwijk CG, ten Cate H, ten Wolde M, ten Cate-Hoek AJ. Biomarkers for post thrombotic syndrome: a case-control study. Thromb Res. 2014 Aug;134(2):369-75. doi: 10.1016/j.thromres.2014.06.010. Epub 2014 Jun 13. PubMed PMID: 24975586.