Het ontstaan van post trombotisch syndroom.

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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.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25244

Bron
Nationaal Trial Register

Verkorte titel
If PTS

Aandoening

Post thrombotic syndrome
Deep venous thrombosis

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre
Overige ondersteuning: European union

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2011
Aantal proefpersonen:	90
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	14-11-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35458
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
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.