

Recidiefrisico van aan voorbijgaande infectie/ontsteking-gerelateerde trombose

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We hypothesize that transient inflammation/infection-associated deep venous thrombosis has a similar recurrence risk as 'classic' provoked deep venous thrombosis.

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

Samenvatting

ID

NL-OMON24747

Bron

NTR

Verkorte titel

BEAST-2

Aandoening

Deep venous thrombosis, diep veneuze trombose

Ondersteuning

Primaire sponsor: UMCG

Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary endpoint, recurrent VTE, will be classified as certain or uncertain, based on the

Toelichting onderzoek

Achtergrond van het onderzoek

Unprovoked venous thrombo-embolism (VTE) has a two to three fold higher risk of recurrence after cessation of anticoagulation therapy, when compared to provoked VTE. Provoked VTE is treated for only three to six months after the elimination of the provoking factor. In unprovoked VTE this cannot be achieved. The initial anticoagulation therapy is therefore extended beyond the three to six months. However, anticoagulation therapy induces a clinically relevant bleeding risk. Therefore, effort should be made to identify patient categories with a lower risk of recurrence within the group of patients with a unprovoked VTE. From 2008 to 2010 the a cohort study, the BEAST, was performed in the University Medical Center Groningen, in which patients at the emergency department presenting with pulmonary embolism and/or thrombosis were asked whether they experienced transient inflammatory/infectious signs (e.g. the flu or a cold) before the onset of the thrombosis. It was shown that these transient inflammation/infection was associated with a higher risk of thrombosis. Currently transient inflammation/infection is not considered as a risk factor for thrombosis, thus thrombosis preceded by these complaints are treated as unprovoked VTE. In this study, we aim to determine and to compare the rate of recurrent VTE in patients with provoked and unprovoked index-VTE preceded and not preceded with transient inflammation/infection-associated index-VTE in the BEAST-cohort.

Doel van het onderzoek

We hypothesize that transient inflammation/infection-associated deep venous thrombosis has a similar recurrence risk as 'classic' provoked deep venous thrombosis.

Onderzoeksopzet

Start of study

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

UMCG
B.S. Bhoelan

Groningen
The Netherlands

Wetenschappelijk

UMCG
B.S. Bhoelan

Groningen
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients with a first proximal DVT (located in the popliteal, femoral or iliacal veins) with or without PE or single PE included in the BEAST-study performed between 2008 and 2010 in the University Medical Center Groningen

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	10-08-2018
Aantal proefpersonen:	194
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	23-08-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5047
NTR-old	NTR7445
Ander register	UMCG Research Registry : 201800412

Resultaten