Recidiefrisico van aan voorbijgaande infectie/ontsteking-gerelateerde trombose

No registrations found.

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

Summary

ID

NL-OMON24747

Source
Nationaal Trial Register

Brief title
BEAST-2

Health condition

Deep venous thrombosis, diep veneuze trombose

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

The primary endpoint, recurrent VTE, will be classified as certain or uncertain, based on the classification used in the Dutch MEGA study (Timp et al. J Thromb Haemost 2015)

Secondary outcome

* Cause of recurrent VTE: provoked or unprovoked (as defined earlier)

* All-cause mortality

* VTE-specific mortality: o VTE reported as cause of death in patient health care database (i.e. medical reports, autopsy reports or correspondence to primary health care physician)

Study description

Background summary

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.

Study objective

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

Study design

Start of study

Intervention

none

Contacts

Public
UMCG
B.S. Bhoelan

Groningen
The Netherlands
Scientific
UMCG
B.S. Bhoelan

Groningen
The Netherlands

Eligibility criteria

Inclusion criteria

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

Exclusion criteria

-

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-08-2018
Enrollment:	194
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-08-2018
Application type:	First submission

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
NTR-new	NL5047
NTR-old	NTR7445
Other	UMCG Research Registry : 201800412

Study results