NOSTRADAMUS: Testing for thrombophilia in patients with a first episode of venous thromboembolism (VTE): a randomized controlled trial to assess effects on clinical outcomes, quality of life, and costs.

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25044

Source
Nationaal Trial Register

Brief title
NOSTRADAMUS

Health condition

First episode of deep vein thrombosis (DVT) or pulmonary embolism (PE).

Sponsors and support

Primary sponsor: ZonMw
Nederlandse Hartstichting (Dutch Heart foundation)

Intervention

Outcome measures

Primary outcome

recurrent VTE 18 months after the acute episode of VTE

Secondary outcome

1. Recurrent VTE at the end of the study

2. A composite endpoint of recurrent VTE and bleeding at the end of the study

3. Quality of life

4. costs of testing and subsequent predefined prolongation of anticoagulant therapy

Study description

Background summary

A randomized controlled trial of testing and no testing for thrombophilia in patients with a first episode of VTE will be performed. Subsequent additional anticoagulant treatment for a predefined period will be installed in those in whom thrombophilia is detected in the testing group, while others will receive a standard predefined duration of treatment. In addition, the impact on quality of life of thrombophilia testing will be measured. Efficacy and safety outcomes are risk for recurrent VTE and clinically important bleeding (also as a composite outcome). Other outcomes are overall quality of life and costs associated with the outcome measures 18 months after the initial episode of VTE. Outcomes will be compared between thrombophilic patients allocated to the testing group and to the no testing group. A total of 1336 patients will have to be included to detect a benefit of 90% by prolonging anticoagulant treatment in patients with thrombophilia while on treatment, and no reduction in the 6 months after cessation of treatment (overall RRR 55%) [power 80%, CI 95%].

Study objective

Testing for thrombophilia after a first episode of VTE with subsequent prolongation of anticoagulant treatment in thrombophilic patients is beneficial in terms of clinical outcomes, quality of life, and costs.

Intervention

Randomization between disclosure and undisclosure of results of thrombophilia screening and subsequent additional anticoagulant treatment for a predefined period will be installed in

those in whom thrombophilia is detected in the disclosure group

Contacts

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Eligibility criteria

Inclusion criteria

1. Subjects must be willing and able to give written informed consent

2. Confirmed symptomatic DVT, i.e., proximal vein or extensive calf-vein thrombosis, involving at least the upper third part of the deep calf veins (trifurcation, AND/OR confirmed symptomatic PE, no longer than 2 months prior to randomization

3. age 18 years or older

Exclusion criteria

1. Previous episodes of DVT or PE

2. Active bleeding or high risk for bleeding contraindicating treatment with LMWH, fondaparinux or VKA

3. Insertion of a caval filter to treat the episode of VTE

4. Active cancer or anti-cancer treatment in the 6 months prior to the acute episode of VTE

5. Life expectancy < 18 months

6. Arterial thrombotic events in the context of a confirmed antiphospholipid antibody syndrome

7. Indications for VKA other than DVT

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-10-2006
Enrollment:	1336
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-09-2006
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	NL773
NTR-old	NTR784
Other	: N/A
ISRCTN	ISRCTN07836779

Study results

Summary results
N/A