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.

Gepubliceerd: 27-09-2006 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25044

Bron
NTR

Verkorte titel
NOSTRADAMUS

Aandoening

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

Ondersteuning

Primaire sponsor: ZonMw
Nederlandse Hartstichting (Dutch Heart foundation)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

recurrent VTE 18 months after the acute episode of VTE

Toelichting onderzoek

Achtergrond van het onderzoek

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%].

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-10-2006
Aantal proefpersonen:	1336
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-09-2006
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	NL773
NTR-old	NTR784
Ander register	: N/A
ISRCTN	ISRCTN07836779

Resultaten

Samenvatting resultaten
N/A