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NOSTRADAMUS: testing for thrombophilia in patients with a first episode of venous thromboembolism: a randomised controlled trial to assess effects on clinical outcomes, quality of life, and costs

Submission date 28/12/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 28/12/2006	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 06/01/2021	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
NOSTRADAMUS: testing for thrombophilia in patients with a first episode of venous thromboembolism: a randomised controlled trial to assess effects on clinical outcomes, quality of life, and costs

Acronym
NOSTRADAMUS

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

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Medical Ethics Board of the Acamdemic Medical Center Amsterdam on September 20th 2006 (ref: MEC 06/216).

Study design
Randomised, controlled, parallel group, multicentre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pulmonary embolism, deep vein thrombosis

Interventions

Randomisation 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.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Recurrent VTE 18 months after the acute episode of VTE.

Secondary outcome measures
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

Overall study start date
01/10/2006

Completion date
01/04/2010

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Subjects must be willing and able to give written informed consent
2. Confirmed symptomatic Deep Vein Thrombosis (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 Pulmonary Embolism (PE), no longer than two months prior to randomisation
3. Aged 18 years or older

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
1336

Key exclusion criteria
1. Previous episodes of DVT or PE
2. Active bleeding or high risk for bleeding contraindicating treatment with Low Molecular Weight Heparin (LMWH), fondaparinux or Vitamin K Antagonists (VKA)
3. Insertion of a caval filter to treat the episode of VTE
4. Active cancer or anti-cancer treatment in the six months prior to the acute episode of VTE
5. Life expectancy less than 18 months
6. Arterial thrombotic events in the context of a confirmed antiphospholipid antibody syndrome
7. Indications for VKA other than DVT

Date of first enrolment
01/10/2006

Date of final enrolment
01/04/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Center (AMC)
Amsterdam
Netherlands
1100 DD

Sponsor information

Organisation
Academic Medical Center

Sponsor details
Department of Vascular Medicine
PO Box 22660
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Sponsor type
Hospital/treatment centre

Website
https://www.amc.nl/web/Zorg.htm

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Research organisation

Funder Name
Netherlands Heart Foundation (NHS, Nederlandse Hartstichting) (The Netherlands)

Funder Name
Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)

Alternative Name(s)
Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	early termination	20/09/2008	06/01/2021	Yes	No