

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/12/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/01/2021	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr S Middeldorp

Contact details

Academic Medical Center (AMC)
Department of Vascular Medicine, F4-276
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 566 5976
s.middeldorp@lumc.nl

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 ThromboEmbolic (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 Academic 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 undisclosed 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

Amsterdam

Netherlands

1100 DD

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