

# 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

<b>Submission date</b> 28/12/2006	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/12/2006	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 06/01/2021	<b>Condition category</b> 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

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## Additional identifiers

## 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 Academic Medical Center Amsterdam on September 20th 2006 (ref: MEC 06/216).

### **Study design**

Randomised, controlled, parallel group, multicentre trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **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(s)**

Recurrent VTE 18 months after the acute episode of VTE.

### **Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Lower age limit**

18 years

**Sex**

Not Specified

**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

**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

## 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?
<a href="#">Other publications</a>	early termination	20/09/2008	06/01/2021	Yes	No