# Safety and feasibility of a diagnostic algorithm combining clinical probability, D-dimer test and ultrasonography in suspected upper extremity deep vein thrombosis: a prospective management study

Published: 24-11-2009
Last updated: 04-05-2024

To prospectively evaluate the safety and feasibility of a diagnostic strategy combining clinical probability, D-dimer testing, (serial) ultrasonography in patients with clinically suspected UEDVT.

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|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Coagulopathies and bleeding diatheses (excl thrombocytopenic) |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON32583

**Source**
ToetsingOnline

**Brief title**
Diagnostic algorithm for upper extremity DVT

### Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

**Synonym**
arm vein thrombosis, upper extremity deep vein thrombosis

**Research involving**

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum
**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** diagnostic algorithm, upper extremity DVT

## Outcome measures

### Primary outcome

The primary endpoint will be the cumulative 3-month incidence of objectively

confirmed symptomatic venous thromboembolic events including UEDVT and PE in

patients with a normal diagnostic work-up.

### Secondary outcome

Not applicable.

# Study description

### Background summary

The reference standard for the diagnosis of upper extremity deep vein thrombosis (UEDVT) is contrast venography. Unfortunately, venography is invasive, often difficult to perform and interpret, and it requires the use of ionizing radiation. The diagnostic work-up of clinically suspected lower extremity deep vein thrombosis is well established and is based on a combined strategy involving clinical probability, D-dimer and imaging tests. It remains unclear whether clinical probability assessment, the D-dimer test, ultrasonography can be safely used as a diagnostic strategy to detect UEDVT.

### Study objective

To prospectively evaluate the safety and feasibility of a diagnostic strategy combining clinical probability, D-dimer testing, (serial) ultrasonography in patients with clinically suspected UEDVT.

### Study design

A prospective, multicenter, management study. There will be 2 visits; one when the patient is included and one telephone call after 3 months.
Patients will be categorized as likely or unlikely to have UEDVT based on a clinical decision rule (CDR). Patients *unlikely* for UEDVT based on the CDR and with normal D-dimer levels will not receive anticoagulant treatment and will be followed-up at 3 months. All patients with a likely CDR or unlikely CDR combined with elevated D-dimer levels will undergo ultrasonography. In case of a negative or indeterminate ultrasonography result and high D-dimer levels, serial testing will be repeated 3-5 days later or in case of progressive complaints. Anticoagulants will be withheld in all patients for whom UEDVT will be excluded by the initial diagnostic work-up.

### Intervention

Not applicable

### Study burden and risks

The diagnostic algorithm used in this study has not been validated yet. This might result in excluding UEDVT in patients while they actually have UEDVT (i.e. false negative results). However, an algorithm like this has been used for years in the diagnostical work-up in patients with suspected deep vein thrombosis of the leg. Moreover, patients are instructed to be aware of complaints suggestive for UEDVT or pulmonary embolism.

## Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

Patients from the emergency department, in and out patient clinic with clinically suspected UEDVT will be eligible for the study.

## Exclusion criteria

- No informed consent obtained
- Legal age limitation (country specific)
- Use of anticoagulants in therapeutic dosages longer than 24 hours prior to randomisation
- Prior vein thrombosis in the same arm
- Life expectancy < 3 month
- Haemodynamic instability
- Previous participation in the study

# Study design

## Design

**Study type:** Observational non invasive

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|---|---|
| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-11-2009 |
| Enrollment: | 100 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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|---|---|
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 |
|---|---|
| CCMO | NL29834.018.09 |