# The pathophysiology of Deep Vein Thrombosis and Post Thrombotic lesions

Published: 07-03-2018
Last updated: 15-04-2024

To investigate inflammatory processes in (sub) acute DVT at a cellular level.

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| **Ethical review** | Approved WMO |
| **Status** | Recruiting |
| **Health condition type** | Embolism and thrombosis |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON53101

**Source**
ToetsingOnline

**Brief title**
The pathophysiology of Deep Vein Thrombosis and Post Thrombotic lesions

### Condition

- Embolism and thrombosis

**Synonym**
deep venous thrombosis, venous thrombo-embolism

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Medisch Universitair Ziekenhuis Maastricht
**Source(s) of monetary or material Support:** Ministerie van OC&W,NWO

### Intervention

**Keyword:** Deep vein thrombosis, Pathofysiology, Post thrombotic syndrome

## Outcome measures

### Primary outcome

Outcomes are correlations between quantified cell profiles in the thrombus and blood leucocyte profiles of patients in relation to thrombus age and thrombus resolution.

### Secondary outcome

A MRI protocol will be optimised for imaging techniques to gather non-invasive information about thrombus age and resolution.

# Study description

### Background summary

Information about local cellular processes involved in thrombus resolution in humans following Deep Venous Thrombosis of the leg (DVT) is scarce. The currently prevaling hypothesis is, that inflammation is an important process in DVT both for thrombus resolution and for the development of post-thrombotic syndrome.

### Study objective

To investigate inflammatory processes in (sub) acute DVT at a cellular level.

### Study design

Single centre observational mechanistic exploratory pilot study with one-time invasive sampling

### Study burden and risks

During the (sub) acute phase of DVT, in patients that will undergo a thrombolysis thrombus material will be harvested and antecubital vena punction for laboratory testing will be performed. Renal function will, if unknown, be determined because of the use of contrast agent for MR examination. No additional visits will be needed, no questionnaires or diaries need to be filled out. Due to the venapunction patients may experience some discomfort and

they will be at a moderate risk for bleeding. No other risks are expected.
There is no group relatedness.

## Contacts

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

**Age**
Adults (18-64 years)

### Inclusion criteria

- Femoro-popliteal thrombosis, objectively confirmed
- Onset of complaints suggestive of DVT<6 weeks
- Informed consent (IC)

### Exclusion criteria

- - < 18 years

- History of GI bleeding within 12 months
- History of CVA/CNS disease within 12 months
- Severe hypertension (>180/100mmHg)
- Pregnancy
- Previous DVT in the affected leg
- Previous deep venous surgery in the affected leg
- Previous interventions of the superficial venous system <12 months
- Known coagulation disorders
- Surgery within two weeks
- Active malignancy
- Diabetes
- Chronic inflammatory diseases or (auto) immune diseases
- Use of anti-inflammatory medication
- Use of statins
- Allergy to contrast agent (Gadovist)
- Contra-indications for MRI

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 06-09-2022 |
| Enrollment: | 20 |
| Type: | Actual |

# Ethics review

Approved WMO

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| Date: | 07-03-2018 |
| Application type: | First submission |

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| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |
| Approved WMO Date: | 29-03-2021 |
| Application type: | Amendment |
| Review commission: | METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht) |

# 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 | NL59253.068.17 |