

# The pathophysiology of Deep Vein Thrombosis and Post Thrombotic lesions

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruiting
<b>Health condition type</b>	Embolism and thrombosis
<b>Study type</b>	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 prevailing 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 puncture 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 venapuncture 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

### Public

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### Scientific

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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

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

### Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 06-09-2022

Enrollment: 20

Type: Actual

## Ethics review

Approved WMO

Date: 07-03-2018

Application type: First submission

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