# Magnetic Resonance Direct Thrombus Imaging for Suspected Thrombosis of Upper Extremity Diagnostic Evaluation (Selene Study)

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Before embarking on a study using MRDTI as sole test to manage clinically suspected UE-DVT, we need to perform a study to determine whether the test has the potential to be useful in patients with suspected UE-DVT. This study has the objective to…

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

## Summary

### ID

NL-OMON50636

**Source**
ToetsingOnline

**Brief title**
Selene study

### Condition

- Embolism and thrombosis

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

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Leids Universitair Medisch Centrum

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** deep vein thrombosis, MRI, upper extremity

## Outcome measures

### Primary outcome

The primary study parameters are the expected sensitivity and specificity of MRDTI for diagnosing acute arm vein thrombosis. The sensitivity of MRDTI is determined by calculating to proportion of scans that are read as "positive for acute arm vein thrombosis" and the specificity is determined by calculating the proportion of scans that are read as "negative for acute arm vein thrombosis".

### Secondary outcome

The secondary endpoints are 1) the optimization of the MRDTI scan sequences 2) the assessment of interobserver agreement between the reviewers

# Study description

### Background summary

The clinical diagnosis of upper extremity thrombosis (UE-DVT) alone is inaccurate. Therefore accurate objective imaging is required to avoid incorrectly concluding that thrombosis is present or absent placing the patient at risk for a pulmonary embolism at the one hand or a *potentially fatal-bleeding at the other hand. Although a clinical algorithm has been created, the diagnosis of UE-DVT poses a clinical challenge. Contrast venography is considered the reference standard for diagnosing UE-DVT. However this technique is invasive and requires radiation exposure. Furthermore in 18% of the patients contrast venography could not be performed. Ultrasonography is noninvasive and does not expose the patients to radiation and intravenous contrast. Compression ultrasonography (CUS) as diagnostic modality for suspected UE-DVT is reliable in anatomic places where compression is
possible with a sensitivity of 96% and specificity of 94%. However if the thrombosis is more centrally located, the accuracy of CUS is poor due to

overlying anatomical structures which limit the possibility of applying compression. Doppler ultrasonography could be used in these area, but visualization of the thrombus is often difficult. Therefore contrast venography is still recommended as diagnostic modality in these patients. CT venography and MR-venography may serve as alternative modalities; however CT still requires contrast medium and exposes the patient to radiation.
Furthermore only limited studies have been performed with the use of MR venography and the studies which evaluated the use of MR venography in suspected UE-DVT were gadolinium enhanced techniques. Magnetic Resonance Direct Thrombus Imaging (MRDTI) has been shown a highly accurate diagnostic method for a first deep vein thrombosis of the legs. The method is based on measurement of the T1 signal which shortens as a result of the formation of methemoglobin in a fresh thrombus. This technique does not require the administration of gadolinium and the acquisition time is short, making this a patient friendly technique. The sensitivity was 97% and specificity 100% for diagnosis of DVT in the legs. However studies have never assessed the reliability of MRDTI in patients with a suspected UE-DVT.

**Study objective**

Before embarking on a study using MRDTI as sole test to manage clinically suspected UE-DVT, we need to perform a study to determine whether the test has the potential to be useful in patients with suspected UE-DVT. This study has the objective to estimate the sensitivity of MRDTI by examining patients with a clinically suspected UE-DVT. We reason that since MRDTI has already been sensitive for DVT of the legs, it should be sensitive for the arms too, since formation of methemoglobin in a thrombus is common to both conditions and normal MRDTI should rule out UE-DVT. On the other hand, if there were few false positive results in patients with definitively ruled out UE-DVT by contrast venography an abnormal result would be diagnostic of UE-DVT.

**Study design**

The Selene study is a prospective diagnostic proof of concept study. The diagnostic management of suspected UEDVT will be according to the usual clinical practice at the enrolling site. All patients with suspected acute UEDVT will be managed according to a standardized protocol, starting with calculation of the clinical decision rule by Constans, followed by a D-dimer test in case of an unlikely clinical probability. In case of unlikely clinical probability and normal D-dimer test, UEDVT is considered to be ruled out. In case of elevated D-dimer concentration or likely clinical probability CUS will be performed. A positive CUS is diagnostic for UEDVT, an inconclusive CUS or negative CUS is followed by venography to definitely rule out UEDVT. All enrolled patients will receive a MRDTI examination within 48 hours of their initial diagnostic testing. In addition, D-dimer tests will be assessed in patients with a likely clinical probability as well. All patients will be

followed for a 90-day (+/-7 days) period for the occurrence of symptomatic venous thromboembolism.
Two groups of consecutive patients will be compared: those with confirmed UEDVT ('group 1') and those in whom suspected UEDVT is ruled out by the algorithm and who had an uneventful follow-up ('group 2'). Before including patients in the two study groups we will include 3 pilot patients with CUS proven UEDVT to optimize the MRDTI sequences used in previous studies for MRDTI of the lower extremities.

### Study burden and risks

Patients receive as extra examination the MRI. There are no known side-effects of MRI examination.

## 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 with a clinically suspected symptomatic acute UEDVT, confirmed or excluded by the diagnostic algorithm according to current clinical practice.
- Aged 18 years and older, willing and able to give informed consent

### Exclusion criteria

Patients are excluded if the duration of the complaints lasted more than 10 days, or if they have suspected ipsilateral recurrent UEDVT, if they have a MRI contra-indication,or if it is impossible to perform MRDTI within 48 hours. Patients with upper-limb amputation and those with a medical condition, associated illness, or co-morbid circumstances that made it unlikely that the study procedure would be completed are also excluded.

## 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: | Completed |
| Start date (anticipated): | 06-12-2016 |
| Enrollment: | 63 |
| Type: | Actual |

## Ethics review

Approved WMO

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| Date: | 17-10-2016 |
| Application type: | First submission |

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| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |
| Approved WMO Date: | 19-08-2020 |
| Application type: | Amendment |
| Review commission: | METC Leiden-Den Haag-Delft (Leiden)<br><br>metc-ldd@lumc.nl |

# 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 | NL58261.058.16 |

# Study results

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| Date completed: | 18-12-2020 |
| Results posted: | 02-11-2021 |
| Actual enrolment: | 46 |

**First publication**
12-05-2021