Performance of direct thrombus imaging by MRI in the diagnosis of acute recurrent deep-vein thrombosis

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The study has the objective to estimate the sensitivity and specificity of DT-MRI in diagnosing acute recurrent deep venous thrombosis.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Embolism and thrombosis
Study type	Observational invasive

Summary

ID

NL-OMON32134

Source
ToetsingOnline

Brief title
Return study

Condition

- Embolism and thrombosis

Synonym
Deep venous thrombosis, thrombosis of the leg

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Diagnosis, MRI, Recurrent deep venous thrombosis

Outcome measures

Primary outcome

The primary study parameters are the sensitivity and specificity of MRDTI for diagnosing acute recurrent DVT. The sensitivity of MRDTI is determined by calculating the proportion of scans that are read as "positive for acute recurrent DVT" in group 1 patients and the specificity is determined by calculating the proportion of scans that are read as " negative for acute DVT" in group 2 patients. "

Secondary outcome

Doesn't apply

Study description

Background summary

The clinical diagnosis of recurrent deep vein thrombosis (DVT) alone is inaccurate. Although several diagnostic algorithms for suspected first DVT have been validated, the diagnosis of recurrent DVT poses a significant clinical dilemma. Venous compression echography(CUS) is the most widely used non-invasive test for the investigation of a suspected first DVT. However, the diagnosis of recurrent DVT by means of CUS is problematic because persistent abnormalities are present in approximately 80% of patients 3 months and 50% of patients 1 year after proximal DVT. Therefore, when a patient with suspected recurrence has a non-compressible venous segment, it can be difficult to determine wether this represents new disease or a residual abnormality from a previous DVT. Measurement of thrombus diameter by CUS has been shown to diagnose recurrent DVT, however inter-observer agreement is poor. CUS is therefore only accurate when recurrent DVT occurs in another venous segment than at the time of the first DVT.
Direct thrombus imaging by magnetic resonance technique (MRDTI) has been shown a highly accurate diagnostic method for first DVT. The method is based on

measurement of the T1 signal which shortens as a result of the formation of methemoglobin in a fresh thrombus. It does not require the injection of gadolinium.
In a proof of principle study, we have shown that over six months the high signal is extinguishing completely in all 35 patients with CUS prove first episode DVT. This signal could thus potentially be used as a conclusive sign of a new DVT when a patient presents with clinically suspected acute recurrent DVT. As a consequence, this test should be negative in the presence of residual abnormalities caused by old, inactive thrombi and positive with new, actively forming thrombi. Therefore, the test has the potentiall to differentiate old from new thrombosis in patients with suspected acute recurrence.

Study objective

The study has the objective to estimate the sensitivity and specificity of DT-MRI in diagnosing acute recurrent deep venous thrombosis.

Study design

The study design is a prospective multicenter study. Two Dutch hospitals participate in this research project, Leiden University Medical Centre and Haga Leyenburg. For this study we'll need two groups of patients, group 1 has to consist of 40 patients with clinically suspected acute recurrent DVT in the ipsilateral leg and group 2 of 40 patients with a history of DVT. The patients are included in a period of 1 year.
Group 1 will receive between 24-48 hours after the CUS a MRI examination and will return after 6 weeks at the outpatient department for a physical examination and a CUS.
The MRIs of group 2 will be scheduled. The MR images are interpreted in a blinded fashion (i.e.without knowledge of group 1 or 2 status) by two experienced readers who are not involved with the patients.

Study burden and risks

The patients of group 1 get as extra examination the MRI. In group 2 patients get a D-dimer test (blood test), compression ultrasonography and MRI. Neither the blood test, the compression ultrasonography and MRI have risks for the patients. Before the patients undergo a MRI, all the contra-indications will be evaluated. There are no known side-effects of a 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

Group 1:
- At least 18 years of age and willing to provide informed consent
- Newly diagnosed second ipsilateral acute DVT with symptom onset within 10 days
- Non-compressibility of the common femoral vein and/or popliteal vein on compression ultrasonography in a segment that is clearly different from the first episode
- Positive D-dimer test;Group 2:
- At least 18 years of age and willing to provide informed consent
- Chronic symptoms of postthrombotic syndrome, but no symptoms of acute DVT
- Complete or partial non-compressibility of 1 or more proximal deep veins on compression ultrasonography
-The last deep vein thrombosis has been longer than 6 months ago
- Negative D-dimer test

Exclusion criteria

- Younger than 18 years of age
- Patients who received an investigational drug within 30 days of enrolment
- Patients who have undergone a study with MRI in the previous 48 hours
- Patients with lower limb amputation
- Patients with a medical condition, associated illness, or co-morbid circumstances that made it unlikely that the study procedure would be completed
- Patients with a MRI contra-indication:
- A pacemaker or subcutaneous defibrillator of the heart
- Clips in the vascular system of the brains
- Metal fragments in the eye
- An hearing aid which cann't be removed
- A neurostimulator which cann't be removed
- An hydrocephalus pump
- Denture which are fixed by magnets
- A metal intrauterine device
- (The possibility of) being pregnant
- Claustrophobic

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-11-2008
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL21889.058.08