Groningen Venous Imaging Study Comparing Ultrasonography with MRI for Evaluation of Presence of Deep Vein Thrombosis
Part 1 - Pilot Study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Observational invasive

Summary

ID

NL-OMON34302

Source
ToetsingOnline

Brief title
VENOUS study - part 1

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Embolism and thrombosis

Synonym
blood clot, deep vein thrombosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 3-point compression ultrasound, Deep venous thrombosis, Direct thrombus imaging, MRI

Outcome measures

Primary outcome

To assess the sensitivity and specificity of MRDTI in diagnosing proximal DVT

compared to CUS

Secondary outcome

To evaluate the quality of images of MRDTI.

To assess the inter-observer variability of the images of MRDTI.

To evaluate the time-interval between presentation with complaints and the

assessment by CUS and MRI.

Study description

Background summary

Accurate diagnosis of deep vein thrombosis (DVT) is important to prevent thrombo-embolic complications on the one hand and to avoid unnecessary anticoagulant treatment on the other hand. Ultrasonography is currently clinical routine in the diagnostic work-up of DVT. Although ultrasonography can diagnose a first episode of proximal (vena femoralis until vena poplitea) DVT accurately, it has several limitations. Often, repeated examinations are needed to detect or exclude DVT and a number of patients eventually undergo MRI examination.

MRI has several advantages over compression ultra sound (CUS). First, MRDTI can evaluate recent and active thrombus formation, in particular when recurrent DVT is suspected. The new MRDTI sequence thus has the potential to differentiate

between remnant abnormalities from a previous episode of DVT and a newly formed thrombus, which may have consequences for the need for anticoagulant treatment. Second, MRI has the possibility of imaging the full venous course from pelvic to calf veins.

Study objective

We aim to evaluate the use of MRDTI in the diagnosis of acute proximal DVT, comparing the findings with CUS. To evaluate the outcome of patients with positive and negative MRDTI and CUS, clinical outcome after 3 months of follow-up will be measured.
The hypothesis of this study is that MRDTI is at least as good as CUS in diagnosing DVT in terms of sensitivity, specificity, diagnostic time interval and number of examinations needed.

Study design

This pilot study is a prospective observational pilot study, with an estimated inclusion time of three months and a number of patients needed of 40.
Patients who present at the emergency department with clinical suspicion of DVT and who are eligible to enter the study will be approached for inclusion. Written informed consent will be obtained.
CUS will be performed upon presentation, as in normal clinical practice. Hereafter, the patient will be scheduled for MRI, preferably while still in the Emergency Room, but at least in 24 hours.
As in routine clinical practice, patients with a proven DVT by CUS will be treated accordingly with anticoagulants by physicians of the department of Hematology, irrespective of the outcome of MRDTI. Thus, the result of the MRDTI will not be considered for treatment. However, patients with a negative CUS and a positive MRDTI will be treated according to the MRDTI, as we would do in normal clinical practice when suspicion of DVT is high but (repeated) CUS is negative.
All patients are seen after three months at the outpatient clinic of Hematology to assess clinical outcome. However, patients with proven DVT are more frequently seen, as in normal clinical practice (at two weeks, three months and six months after diagnosis of DVT). When a patient returns to the hospital due to persistent complaints or new suspicion of DVT despite negative prior examinations, both ultrasound and MRDTI will be repeated. After inclusion of 40 patients, the pilot study will be closed, and analysis will be performed.

Study burden and risks

Risks of ultrasonography: none documented. Risks of MRDTI: none documented. The burden for patients included in the study will consist of one non-invasive examination by MRI for every examination by ultrasonography, which may thus

involve one extra visit to the hospital or extra waiting time.

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

Age * 18 years old
Willing and able to provide informed consent
Wells score *2 and/or D-dimer * 500

Exclusion criteria

Metal implants, pacemaker

Weight * 160 kg
Claustrophobia
History of DVT or PE

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	24-09-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL33728.042.10