MAGNetic Resonance Direct Thrombus Imaging for Suspected Thrombosis of Upper Extremity Diagnostic Evaluation (MAGNITUDE Study)

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Magnetic Resonance Direct Thrombus Imaging (MRDTI) can be an accurate test for diagnosing Upper Extremity Deep Vein thrombosis (UEDVT)

Ethische beoordeling	Niet van toepassing
Status	Anders
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20594

Bron
NTR

Verkorte titel
MAGNITUDE

Aandoening

Upper Extremity Deep Vein Thrombosis

Ondersteuning

Primaire sponsor: Leiden University Medical Center (LUMC), Leiden
Overige ondersteuning: initiator=sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The sensitivity and specificity of MRDTI for the diagnosis of UEDVT

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

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 1000% for diagnosis of DVT in the legs. However studies have never assessed the reliability of MRDTI in patients with a suspected UE-DVT.

Objective of the study: Klik voor meer informatie

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 MAGNITUDE study is a prospective diagnostic evaluation cohort 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’).

Study population:

Patients are potentially eligible if they are at least 18 years of age and able and willing to provide informed consent. An upper extremity thrombosis is defined as a thrombosis in the axillary, subclavian, jugular and/or brachiocephalic vein. Patients are excluded if the duration of the complaints lasted more than 10 days, if they have a MRI contra-indication, 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. All patients eligible for the study without an exclusion criterium receive a MRDTI examination within 48 hours.

Primary study parameters/outcome of the study:

The primary study parameters are the sensitivity and specificity of MRDTI for diagnosing acute arm vein thrombosis. The sensitivity of MRDTI is determined by calculating te 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".

The secondary endpoints are 1) the interobserver agreement between the reviewers; 2) the sensitivity, specificity, negative predictive value and positive predictive value of the clinical prediction rule and D-dimer test; 3) subgroup analysis for inpatient and outpatient groups, patients with and without malignancy and UEDVT that is and is not secondary to a central venous catheter.

Doel van het onderzoek

Magnetic Resonance Direct Thrombus Imaging (MRDTI) can be an accurate test for

diagnosing Upper Extremity Deep Vein thrombosis (UEDVT)

Onderzoeksopzet

Visit 1: enrolment

Visit 2: MRDTI (within 48 hours of visit 1)

Visit 3: 90-day follow-up

Onderzoeksproduct en/of interventie

The MAGNITUDE study is a prospective diagnostic evaluation cohort 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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) A clinically suspected symptomatic acute UEDVT;

2) Onset of symptoms <10 days;

3) Aged 18 years and over;

4) Willing and able to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Suspected ipsilateral recurrent UEDVT (previous UEDVT objectively diagnosed in the same arm);

2) MRI contra-indication (including but not limited to a cardiac pacemaker or subcutaneous defibrillator; vascular clips in the cerebral vessels; metal splinter in the eye, a hearing aid that cannot be removed; a neurostimulator that cannot be removed; a hydrocephalus pump);

3) Unable to perform MRI within 48 hours;

4) Other indication for therapeutic anticoagulation.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-08-2016
Aantal proefpersonen:	63
Type:	Onbekend

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36551
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5410
NTR-old	NTR5738
CCMO	NL35218.058.11
OMON	NL-OMON36551

Resultaten