Magnetic Resonance Direct Thrombus Imaging for diagnostic management of suspected pelvic vein thrombosis during pregnancy

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We hypothesize that DVT can be safely ruled out by the LEFt rule in combination with the D-dimer test in 5-10% of pregnant women, and that a normal MRDTI safely rules out isolated pelvic vein thrombosis. We hypothesize that 7-10% of performed MRDTI'…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20771

Bron
NTR

Verkorte titel
Tethys

Aandoening

Deep vein thrombosis

Ondersteuning

Primaire sponsor: N.A.
Overige ondersteuning: This is an academic sponsored trial.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Frequency of positive MRDTI findings in pregnant women with suspected pelvic vein thrombosis but negative single CUS (efficiency outcome).

Toelichting onderzoek

Achtergrond van het onderzoek

The Tethys study is a prospective cohort study that will primarily focus on pregnant women with clinically suspected DVT, a high pre-test probability as determined by the LEFt criteria, a positive D-dimer test but negative single CUS. These patients who are thus suspected of pelvic vein thrombosis, will be subjected to MRDTI within 48 hours of clinical presentation and initial diagnostic testing. Moreover, a small number of patients with 0 or 1 LEFt points in combination with a normal D-dimer test will be subjected to MRDTI as well. In the former patient category, MRDTI will be applied as definite diagnostic test, and patients will be treated based on the result of the MRDTI. In the latter patient category, MRDTI will only be read post-hoc, and its results will not influence the therapeutic management of the patient, since DVT has been ruled out based on the initial tests performed. All patients will be followed for a 90-day (+/-7 days) period for the occurrence of symptomatic VTE as part of the LEAD study.

The Tethys study will be performed in close collaboration with the LEAD study (NCT02507180), a running prospective cohort diagnostic management study in pregnant women with suspected DVT. The primary outcome of this study is to assess the number of VTE events, i.e. any DVT (distal or proximal), pulmonary embolism ([PE] sub-segmental or greater PE), or death potentially attributable to VTE, during the three-month follow-up in those patients left untreated for DVT on the basis of an "unlikely" LEFt score (0 or 1 points) and a negative D-dimer test result. This study aims to include 366 patients to ensure that the lower bound of the 95% confidence interval for the failure rate of the diagnostic strategy is less than 3% (3/300; 1% (95% CI: 0.3 to 2.9%) assuming a point estimate of a 3-month VTE risk of 1% in patients left untreated after completion of the initial diagnostic strategy. In this collaboration, the data of both studies will be combined for the calculation of the main outcomes of LEAD, being secondary outcome 2 and 3 of the Tethys study.

Doel van het onderzoek

We hypothesize that DVT can be safely ruled out by the LEFt rule in combination with the D-dimer test in 5-10% of pregnant women, and that a normal MRDTI safely rules out isolated pelvic vein thrombosis. We hypothesize that 7-10% of performed MRDTI’s in the patients with high pre-test probability, abnormal D-dimer test but normal CUS will show isolated pelvic vein thrombosis, while MRDTI is negative in the patients in whom DVT is ruled out without imaging

Onderzoeksopzet

All patients will be followed for 3 months.

Onderzoeksproduct en/of interventie

MRDTI as decisive diagnostic test in preganant patients with suspected isolated pelvic vein thrombosis

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

 Pregnant women with suspected DVT, defined as i) new leg swelling or edema with onset in the last month or ii) new leg pain (buttock, groin, thigh or calf) with onset in the last month; pregnancy is defined as a positive pregnancy test and no sign of miscarriage
 Onset of symptoms more than 24 hours but less than 10 days ago
 Aged 18 years or older
 Willing and able to give written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

 Concomitant symptoms of suspected PE (chest pain or shortness of breath or syncope/pre-syncope or unexplained tachycardia)
 Therapeutic anticoagulant therapy more than 48 hours prior to inclusion (thrombosis prophylaxis is allowed)
 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; claustrophobia)
 Unable to perform MRI within 48 hours
 A medical condition, associated illness or co-morbid circumstances that precludes completion of the study procedures (MRI and 90-day follow-up assessment), including but not limited to life-expectancy less than 3 months, inability to lie flat or morbid obesity preventing use of MR.
 Any reperfusion therapy (e.g. thrombolysis, surgical clot removal) initiated for the current suspected VTE diagnosis applied before subjecting the patient to MRDTI.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2019
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	31-01-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7498
Ander register	: ABR research file number NL68905.098.19

Resultaten