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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20771

Source
NTR

Brief title
Tethys

Health condition

Deep vein thrombosis

Sponsors and support

Primary sponsor: N.A.
Source(s) of monetary or material Support: This is an academic sponsored trial.

Intervention

Outcome measures

Primary outcome

Frequency of positive MRDTI findings in pregnant women with suspected pelvic vein

thrombosis but negative single CUS (efficiency outcome).

Secondary outcome

1. Number of VTE events occurring in pregnant women with suspected pelvic vein thrombosis who remained untreated based on a normal MRDTI result (safety outcome).
2. Number of VTE events occurring in pregnant women in whom DVT is ruled out by combination of LEFt criteria and D-dimer test (safety outcome).
3. Number of patients with 0-1 LEFt criteria and a normal D-dimer test (efficiency outcome).
4. Frequency of positive MRDTI findings in patients with suspected DVT during pregnancy in whom this diagnosis was ruled out by combination of LEFt criteria and D-dimer test.
5. Kappa-statistic of the combined MRDTI reading from both study cohorts between 2 experienced radiologists (post-hoc).

Study description

Background summary

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.

Study objective

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

Study design

All patients will be followed for 3 months.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

 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

Exclusion criteria

 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2019
Enrollment:	150
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	31-01-2019
Application type:	First submission

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
NTR-new	NL7498
Other	: ABR research file number NL68905.098.19

Study results