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

Published: 14-05-2019
Last updated: 20-06-2024

Zie protocol, hoofdstuk 3 (Objectives)

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Coagulopathies and bleeding diatheses (excl thrombocytopenic)
Study type	Interventional

Summary

ID

NL-OMON52728

Source
ToetsingOnline

Brief title
Tethys study

Condition

- Coagulopathies and bleeding diatheses (excl thrombocytopenic)
- Maternal complications of pregnancy

Synonym
Thrombosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Diagnosis, MRI, Pelvic vein thrombosis, Pregnancy

Outcome measures

Primary outcome

Zie protocol, hoofdstuk 3 (Objectives)

Secondary outcome

Zie protocol, hoofdstuk 3 (Objectives)

Study description

Background summary

Zie protocol, hoofdstuk 1 & 2 (Introduction & Background and rationale)

Study objective

Zie protocol, hoofdstuk 3 (Objectives)

Study design

Zie protocol, hoofdstuk 6 (Methods)

Intervention

Zie protocol, hoofdstuk 6&7 (Methods & Specific methods)

Study burden and risks

Both the risks and the burden for the study participants are minimal. Some will be asked to be subjected to a short (and harmless) MRDTI scan. Considering the current literature, it is our strong hypothesis that the risk of a missed diagnoses of venous thromboembolism by applying the study algorithm is very low.

Contacts

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Trial sites

Listed location countries

Netherlands

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 phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-11-2019
Enrollment:	90
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	14-05-2019

Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO Date:	19-02-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	28-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	29-01-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	29-04-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	21-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Approved WMO Date:	06-05-2022

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	15-04-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL68905.058.19
Other	Trial NL7498 (NTR)