Optimizing diagnosis of abdominal vein thrombosis with MRI- the Rhea study

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21809

Source
NTR

Health condition

- non-symptomatic chronic (incidental) splanchnic vein thrombosis (SVT)
- acute splanchnic vein thrombosis (SVT)
- portal vein thrombosis (PVT)
- mesenteric vein thrombosis (MVT)
- splenic vein thrombosis (SpVT)
- Budd-Chiairi syndrome (BCS)

Nederlands:
- asymptomatische chronische (incidentele) buivene trombose
- acute buikvene trombose
- poortader trombose
- mesenteriale vene trombose
- Milt vene trombose
- Budd-Chiairi syndroom (BCS)

Sponsors and support

Primary sponsor: LUMC (Leids Universitair Medisch Centrum)
Source(s) of monetary or material Support: SCC-ISTH

Intervention

Outcome measures

Primary outcome

To explore the diagnostic accuracy of MRDTI in the diagnostic management of acute and chronic SVT in a prospective diagnostic proof of concept study

Secondary outcome

1) To optimise MRDTI sequences for imaging SVT.

2) To assess the interobserver agreement of the readers of MRDTI for suspected SVT.

Study description

Background summary

Splanchnic vein thrombosis (SVT) includes portal vein thrombosis, mesenteric vein thrombosis, splenic vein thrombosis and the Budd-Chiari syndrome (Riva et al, Thromb Res 2017). There is no validated clinical algorithm for the diagnosis of SVT and there are no specific laboratory tests. D-dimer cannot be used due to the high rate of false positive results, especially in patients with cirrhosis, cancer, or underlying inflammatory conditions, present in more than half of the total SVT population (Dai et al, Int J Clin Exp Med 2015). Whereas Doppler ultrasound is the imaging test of choice for most forms of SVT, its sensitivity is only 90%, as is the sensitivity of CT angiography (Riva et al, Thromb Res 2017; Garcia-Pagán et al, J Hepatol 2015). MR angiography has been reported to have 90-100% sensitivity for SVT, but this technique is limited by the need to administer a contrast agent. Moreover, it may take >60 minutes to complete the scan.

Importantly, many of SVT diagnoses in clinical practice (up to 30%) are incidental findings in asymptomatic patients (Thatipelli et al, Clin Gastroenterol Hepatol 2010). Whereas the diagnosis of symptomatic SVT is often challenging, the correct diagnosis of acute versus chronic incidental SVT is even more difficult, as neither of the current available imaging tests is helpful in determination of the age of the clot. Due to this impossibility to determine whether the incidentally observed thrombosis is acute, chronic or even an imaging artefact, the vast majority of patients with incidental SVT are treated with -often lifelong- anticoagulants. It is widely acknowledged that this practice likely results in overdiagnosis and unjust exposure to anticoagulant therapy with associated risk of bleeding.

An alternative imaging technique for more accurate diagnosis of SVT is MR Direct Thrombus Imaging (MRDTI). This technique is in an advanced stage of development (Theia study, NCT02262052, supported by TSN grant 2013-02) and is close to implementation in clinical practice. The method is based on the formation of methemoglobin in a fresh thrombus leading to shortening of the T1 signal. It does not require contrast dye. Both the diagnostic accuracy (sensitivity 97-100%, specificity 100%) as well as the inter-observer agreement of MRDTI for first and recurrent DVT of the leg were reported to be excellent (kappa 0.89-0.98) (Fraser et al, Ann Intern Med 2002; Tan et al, Blood 2014). Moreover, it was shown to accurately differentiate acute from chronic thrombosis (Tan et al, Blood 2014).

The primary objective of this study is to prospectively evaluate the diagnostic accuracy of MRDTI for acute SVT and to assess interobserver agreement of expert readers. This will be achieved by performing MRDTI scans in 35 patients with confirmed acute SVT as well as in 35 patients with confirmed, non-symptomatic chronic SVT, as defined by incidental SVT treated for at least 3 months and with chronic thrombi on 2 serial imaging tests with at least 3 months interval. All scans will be evaluated post-hoc by expert readers blinded for the final diagnosis. This study design was successfully applied to evaluate the accuracy and reproducibility of MRDTI for suspected DVT of the leg (Tan et al, Blood 2014). This study will be performed in cooperation with Prof. Walter Ageno (University Hospital Varese, Italy) and Prof. Frank Leebeek (Erasmus MC Rotterdam), both world leading experts in this field.

Study objective

Primary hypothesis is that MRDTI will demonstrate acceptable sensitivity and specificity for the diagnosis of acute SVT and the differentiation between acute and chronic SVT.

Study design

Visit 0 (clinical assessment):

- Doppler ultrasound, CT or MRI of the abdomen (Part of clinical practice, no study proceedings)

- Treatment decision (Part of clinical practice, no study proceedings)

Visit 1 (enrolment):

- check for in- and exclusion criteria

- obtain informed consent

- medical history

- clinical examination

- Lab test (d dimer, renal function) (Part of clinical practice, no study proceedings)

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

- MRDTI of abdomen

Visit 3 (90 day follow up)

- recording of death, major bleeding, hospital admission or symptomatic SVT or VTE

Trial schedule:

Year 1: finisch study protocol, permission MEC, MRDTI scans to adjust and optimize the DTI scan sequence in 3-5 patients with confirmed, acute SVT, instructing other study sites, including 5-15 patients

Year 2: including 30-50 patients

Year 3: including 5-35 patients, blind evaluation post hoc of MRDTI scans, analyse data, writing article and submit manuscript

Intervention

This study is a prospective diagnostic proof of concept study to explore the diagnostic accuracy of MRDTI in the diagnostic management of acute and chronic SVT. This will be achieved by performing MRDTI scans to adjust and optimize the DTI scan sequence in 3-5 patients with confirmed, acute SVT. If a reproducible clearly positive DTI signal is achieved in all patients, the study can proceed with the inclusion of cohort 1 and 2, i.e. 35 patients with confirmed acute SVT and in 35 patients with confirmed, chronic SVT. All scans will be evaluated post-hoc by expert readers blinded for the final diagnosis. It is predetermined that at least five patients of each SVT site (PVT, MVT, SpVT and BCS) and at least five patients of each SVT risk factor (oncologic, post-surgical and inflammatory/infectious) will be included. To make sure that cohort 1 is generally similar to cohort 2, the last 10 patients with acute SVT will be included by matching with the last 10 included controls, according SVT site and SVT risk factor.

Contacts

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Eligibility criteria

Inclusion criteria

- Patients with confirmed acute SVT; definitions provided in paragraph 4.2 (Cases, group 1)

- Patients with confirmed non-symptomatic chronic SVT, defined by incident SVT treated for at least 3 months and with chronic thrombi on 2 serial imaging tests with at least 3 months interval (controls, group 2)

- Aged 18 years and older

- Willing and able to give informed consent

Exclusion criteria

- 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)

- 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, morbid obesity preventing use of MR and claustrophobia.

- Patients with decompensated liver disease with ascites (since MRDTI evaluation will be inadequate in these patients)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2018
Enrollment:	73
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL6883
NTR-old	NTR7061
Other	: Protocol Version: 1.2, 2018-02-14

Study results

Summary results
none