Transjugular Intrahepatic Portosystemic Shunt (TIPS): accuracy of MR Flow mapping in the detection of shunt abnormalities.

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Primary Objective:Validate the accuracy of:· MR Flow mapping in measuring PPG in patients with GoreTex®-covered TIPS as compared to the gold standard, portography.· MRA for establishing TIPS patency as compared to Doppler US and using invasive...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatic and hepatobiliary disorders
Study type	Observational invasive

Summary

ID

NL-OMON31137

Source
ToetsingOnline

Brief title
TIPS MR Follow-up

Condition

- Hepatic and hepatobiliary disorders

Synonym
liver cirrhosis, transjugular intrahepatic portosystemic shunt

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: MR Flow mapping, Portosystemic pressure gradient, TIPS

Outcome measures

Primary outcome

Accuracy of MR flow mapping to measure PPG, using invasive pressure measurements of PPG, portography, in patients with a GoreTex®-covered TIPS.

Accuracy and comparison of MR angiography, MR flow mapping and Doppler US to detect shunt dysfunction of GoreTex®-covered TIPS using invasive portography as gold standard.

Secondary outcome

o Patient acceptability with each technique.

o Interobserver agreement in analysis of the MRI data and Doppler US data.

Study description

Background summary

Patients with a transjugular intrahepatic portosystemic shunt (TIPS) have portography or Doppler ultrasonography regularly (about once a year) as a control for shunt dysfunction. Portography is the gold standard, but this procedure is invasive and therefore burdensome for the patient. Doppler US is difficult to perform and highly dependent on operator*s skill. Therefore, a test is needed that is less invasive than portography and easier to perform and interpret than Doppler US. CT angiography has proven to be accurate for this purpose. This, however, requires ionizing radiation and iodinated contrast agents.
MR flow mapping can measure flow volumes. With flow volumes within the stent the porto-systemic pressure gradient (PPG) can be calculated by Poiseuille*s Law Calculation (protocol page 4).
Vasovist is the first intravascular contrast agent approved for use with Magnetic Resonance Angiography in the European Union. Vasovist is an optimal

contrast agent for detection of structural abnormalities, such as stenosis, in the vasculature.
We propose that MR flow mapping can be used in measuring PPG and MRA (with Vasovist) can be used as a screening device for shunt dysfunction.

Study objective

Primary Objective:
Validate the accuracy of:
· MR Flow mapping in measuring PPG in patients with GoreTex®-covered TIPS as compared to the gold standard, portography.
· MRA for establishing TIPS patency as compared to Doppler US and using invasive portography and portal venous pressure measurements as gold standard.

Secondary Objective:
Determine
· Patient acceptability with each technique.
· Interobserver variability in analysis of the MRI- and Doppler US data.

Study design

A validation study. Patients with a GoreTex®-covered TIPS will have MR flow mapping and MRA with Vasovist, which will be compared with portography and Doppler US.

Study burden and risks

Within the scope of this study patients with a Gore-Tex®-covered TIPS will have an MRA and MR Flow mapping with Vasovist, in addition to the standard care consisting of portography and Doppler US, which will be performed twice. The risks of MRA and MR flow mapping with Vasovist are negligible.
We expect that this study will provide the foundation for the future implementation of MR flow mapping with contrast in measuring PPG and of MRA as screening device for shunt abnormalities, providing a less burdensome modality to the entire patient population.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with a GoreTex®-covered TIPS
Age>18 years
Informed consent

Exclusion criteria

Age<18 years
Any contraindication to MRI:
- pacemaker
- cerebral aneurysm clip
- cochlear implant
- presence of metal/shrapnel in strategic locations such as the eye
- claustrophobia
- not being able to remain lying down for at least 45-60 minutes (e.g. patients with unstable angina, dyspnea at rest, severe pain at rest, severe back pain)
Any contraindication to the administration of the contrast agent Vasovist
Severe renal impairment (clearance < 20 ml/min)
Hemodynamically unstable
Severe hepatic encephalopathy (grade III and IV)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2007
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	15-10-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL18162.078.07