Quantitative Magnetic Resonance imaging modalities in the assessment and determination of PORTAL hypertension study

Published: 22-05-2024
Last updated: 19-04-2025

The study aims to determine the feasibility and diagnostic accuracy of quantitative Magnetic Resonance Imaging (MRI) techniques for determining the presence of portal hypertension in patients with severe liver disease. The secondary objectives are...

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

Summary

ID

NL-OMON56775

Source
ToetsingOnline

Brief title
MR PORTAL study

Condition

- Hepatic and hepatobiliary disorders
- Vascular therapeutic procedures
- Vascular hypertensive disorders

Synonym
Increased portal pressure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Financial support from Kingdom of Saudi Arabia (scholarship for PhD)

Intervention

Keyword: Diagnosis, Hypertension, MR, Portal

Outcome measures

Primary outcome

• The diagnostic accuracy of TMRE for assessing portal hypertension severity.

Secondary outcome

• Correlation of TMRE results (stiffness and viscosity) with HVPG pressure

gradient measurements in patients with portal hypertension.

• Correlation of TMRE results with US elastography measurements.

• Correlation of TMRE results with ASL perfusion data.

• Characterisation of TMRE in normalization of portal hypertension after

medicinal or endovascular treatment.

• The feasibility of novel synthetic MRI (SyMRI).

Study description

Background summary

Hepatic vein pressure gradient (HVPG) measurements are currently the reference standard for evaluating the portal pressure. In clinical practice, however, other non-invasive methods with low diagnostic accuracy are used. More reliable non-invasive imaging techniques for diagnosis of portal hypertension and follow-up of portal pressure in time are needed.

Study objective

The study aims to determine the feasibility and diagnostic accuracy of quantitative Magnetic Resonance Imaging (MRI) techniques for determining the presence of portal hypertension in patients with severe liver disease. The secondary objectives are to correlate tomoelastography results (stiffness and viscosity) with elastography measurements, to correlate tomoelastography results with HVPG pressure gradient measurements, and to investigate if tomoelastography can assess normalization of portal hypertension after medicinal or endovascular (transjugular intrahepatic portosystemic shunt (TIPS)) treatment.

Study design

This study is a single centre, prospective study to determine the feasibility and diagnostic accuracy of quantitative MRI techniques in 20 healthy volunteers, 40 patients with liver cirrhosis and known to have portal hypertension of which 20 patients with moderate portal hypertension and 20 patients with severe portal hypertension.

Study burden and risks

The risks and burden associated with participating in this study are very low. Patients and healthy volunteers will undergo an additional MRI investigation as part of this study. As there is no use of radiation, there is no subsequent risk of exposure to radiation during an MRI procedure. Subjects with implanted medical devices will not receive an MRI exam unless the implanted medical device has been positively identified as MR Safe or MR Conditional. An MR Conditional device will only be considered safe if the MR environment matches its conditions for safe use. There is no direct benefit from this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Patients with liver disease:
• Patients of more than 18 years of age
• Written informed consent
• Patients with clinically proven portal hypertension due to chronic liver disease, either moderate (history of oesophageal varices grade 2/3 without use of beta-blockers as pharmaceutical treatment) or severe (recurrent oesophageal variceal bleeding, therapy-resistant ascites)

Healthy controls:
• Patients of more than 18 years of age
• Written informed consent
• No known liver disease by means of liver function test/ultrasound

Exclusion criteria

- Absolute contraindications to MR imaging
- Hepatocellular carcinoma or liver metastases

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-11-2024
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	THEA Devices VibroR42
Registration:	No

Ethics review

Approved WMO Date:	22-05-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-02-2025
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL74470.042.23