Non-Invasive Portal and Hepatic Vein Pressure Estimation: MRI-Guided Diagnostics for Chronic Liver Disease

Published: 20-11-2023
Last updated: 30-11-2024

The primary objective is to develop and validate non-invasive portal pressure measurement by MRI in patients with end-stage liverdisease (ESLD).

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

Summary

ID

NL-OMON56118

Source
ToetsingOnline

Brief title
NONEEDLES

Condition

- Hepatic and hepatobiliary disorders

Synonym
end-stage liver disease, liver cirrhosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic liver disease, MRI, non-invasive diagnostic, portal hypertension

Outcome measures

Primary outcome

The aim of the study is to compare non-invasive PH measurement by 4D flow MRI

and CFD modelling with HVPG measurements

using the transjugular approach in patients with end-stage liver disease

screened for OLT.

Secondary outcome

Secondary objectives are cost effectiveness, safety, feasibility and efficacy

of 4D flow MRI and CFD modelling.

Study description

Background summary

Portal hypertension (PH) is a spectrum of complications of end-stage liver disease (ESLD) and cirrhosis, with severe manifestations including ascites and gastroesophageal varices. It is therefore important that timely and easily diagnosing PH has relevant prognostic and therapeutic implications. The current gold standard to evaluate PH is by hepatic vein catherization using the transjugular approach, and measuring the hepatic venous pressure gradients (HVPG).
Time-resolved, three-dimensional, three-directional velocity-encoded MRI, also termed four-dimensional (4D) flow MRI, has been shown superior accuracy over conventional two-dimensional (2D) phase-contrast MRI, in particular for quantification of regurgitant volumes and severity of cardiac shunts. Recently, we developed new imaging methods based on 4D flow MRI for visualization of the vasculature of the abdominal blood flow circulation including the portal vein. Using our newly developed computation fluid dynamics (CFD) model we could determine the absolute local blood pressure in the portal vein. Preliminary data in healthy volunteers seem promising, however, data in patients with ESLD including the correlation with invasively measured HVPG are lacking.

Study objective

The primary objective is to develop and validate non-invasive portal pressure measurement by MRI in patients with end-stage liver disease (ESLD).

Study design

In 50 adult patients with ESLD, submitted for liver transplantation (LT) screening, HVPG measurements using the transjugular approach according to the standard LT screening protocol, will be extended by 4D flow MRI measurements.

Study burden and risks

Patients will undergo a single non-invasive MRI-examination of one hour long after a six hour period of fasting. The risks associated with non-invasive MRI examinations is neglectable.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2223ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2223ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Eligable for liver transplantation (LT) screening
- Age >= 18 years and <= 75 (since >75 is a contraindication for LT)
- Written informed consent

Exclusion criteria

- Exclusion criteria for MRI (claustrophobia, pacemaker, metal implants, etc.)
- A psychiatric, addictive or any other disorder that compromises the subjects ability to understand the study content and to give written informed consent for participation in the study

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-02-2024
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	MRI 4D-flow application
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-11-2023
Application type:	First submission
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	NL85208.058.23