# 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**

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#### Scientific

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# **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