

MR Elastography of the liver: Voxel-wise precision of viscoelasticity measurements at 3 Tesla MRI

Published: 23-09-2010

Last updated: 30-04-2024

To calculate the repeatability and reproducibility of MRE stiffness measurements in the liver on a voxel-by-voxel basis.

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

Summary

ID

NL-OMON34573

Source

ToetsingOnline

Brief title

Precision of MR Elastography

Condition

- Hepatic and hepatobiliary disorders

Synonym

chronic liver diseases

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Nuts-ohra

Intervention

Keyword: elastography, Liver, MRI, precision

Outcome measures

Primary outcome

The voxel-wise variability in elasticity measurements for patients and healthy volunteers for:

- * Repeated measurements during one scanning session
- * Same-day reproducibility
- * Reproducibility with a 2-4 week interval

Secondary outcome

NA

Study description

Background summary

Magnetic Resonance Elastography (MRE) is a new non-invasive method to evaluate liver fibrosis by measuring liver stiffness. A non-invasive tool for measuring liver fibrosis is important as the current gold standard, liver biopsy, has many drawbacks. It is invasive, has a risk of complications, is prone to sampling errors and inter-observer variability of the pathologist. Due to these drawbacks, liver biopsy cannot be used to monitor patients with chronic liver diseases. To date, the findings of MRE have been studied in a wide spectrum of chronic liver diseases and have shown to be promising. Reproducibility of findings, however, have not been investigated much, and never for 3T MRI. Investigating the precision of stiffness values measured is important when the technique is to be used as a follow-up tool to evaluate treatment response or disease progression.

Study objective

To calculate the repeatability and reproducibility of MRE stiffness measurements in the liver on a voxel-by-voxel basis.

Study design

This is a single centre, observational study

Study burden and risks

Participating in this study leads to no immediate advantage for the individual participant. However, it is important to evaluate the precision of this new MR technique when it is to be used in clinical practise. Therefore in the future, patients with chronic liver disease may benefit considerably by this new diagnostic modality. All participants in this study will receive a financial compensation of 75 euros for completing both MRI scans.

MR Elastography will be performed during two MRI sessions of approximately 30-40 minutes each. MR Elastography is a non-invasive, non ionizing examination and has no physical burden, except that during scanning the patient will have to lie still on his or her back. Patients will also have to hold their breaths on expiration for 10 seconds each time. Patients can indicate when they are ready for the next breath hold. From experience, patients do not find it hard to follow and perform these instructions. The vibrations of the MRE transducer are felt, but do not cause discomfort or pain. Each scanning session will require an extra visit to the hospital. No oral or intravenous contrast medium will be given to the patient. Patients are not delayed in treatment for their disease. There will be little extra physical and psychological discomfort associated with participation.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients:

**18 years of age

*Known chronic liver disease

*Not on treatment for liver disease during study period

*Written informed consent;Volunteers:

*No history of liver disease

*Written informed consent

Exclusion criteria

Patients/Volunteers:

*Under 18 years of age

*Contra-indications for MRI scanning (use of standard MRI checklist, see document E4)

*Treatment for liver disease

Use of medications known to have steatogenic effects on the liver: synthetic estrogens, corticosteroids, diltiazem, nifedipine, perhexilline, amiodarone, metformine, insulin, statins, rosglitazon, methotrexate, antiretroviral therapy, tamoxifen, tetracycline, valproate

*Known hemochromatosis

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Pending
Start date (anticipated): 01-09-2010
Enrollment: 40
Type: Anticipated

Ethics review

Approved WMO
Application type: First submission
Review commission: METC Amsterdam UMC

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	NL32598.018.10