MR Elastography versus FibroScan for the non-invasive assessment of liver fibrosis in patients with chronic liver disease

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To assess the diagnostic accuracy of MR Elastography in detecting and monitoring different degrees of liver fibrosis compared to FibroScan and histopathology in patients with suspected chronic viral liver disease and non-alcoholic fatty liver...

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

Summary

ID

NL-OMON33250

Source
ToetsingOnline

Brief title
MR elastography

Condition

- Hepatic and hepatobiliary disorders

Synonym
liver fibrosis, scarring of liver parenchyma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: Chronic viral liver disease, FibroScan, MR elastography, Non-alcoholic fatty liver disease

Outcome measures

Primary outcome

Assessment of the diagnostic accuracy of MR Elastography in diagnosing liver fibrosis compared with FibroScan and histopathology in patients suspected of chronic viral liver disease and non-alcoholic fatty liver disease.

Secondary outcome

*The feasibility of combining MR Elastography and proton MR Spectroscopy in non-alcoholic fatty liver disease to distinguish between simple steatosis and NASH.

*The evaluation of antiviral treatment response with combined MR Elastography and MR Spectroscopy versus FibroScan in patients with chronic viral liver disease.

*The influence of increased hepatic fat content and inflammatory activity on viscoelasticity measurements.

*The burden of liver biopsy, MR Elastography and FibroScan.

Study description

Background summary

The prognosis of patients with chronic liver disease depends to a high degree on the presence and degree of liver fibrosis. In this respect determination of different degrees of liver fibrosis is crucial for the management of chronic

liver disease. Liver biopsy is the current gold standard for diagnosing chronic liver disease. However, liver biopsy is accompanied by the risk of complications, patient discomfort and poor reproducibility due to sampling errors. Transient Elastography (FibroScan) is now used as a non-invasive alternative to detect liver fibrosis by measuring liver stiffness. This ultrasound technique can differentiate between severe liver fibrosis and no fibrosis, but is not sensitive enough to measure lower degrees of liver fibrosis. Furthermore, increased hepatic fat content and inflammatory activity has a possible confounding effect on the fibrosis measurement. Magnetic Resonance Elastography (MRE) has been introduced as a new and accurate non-invasive method to determine liver fibrosis. MRE provides reproducible viscoelastic information of the whole liver, and is not prone to sampling errors. However, the findings of MRE have been studied in a wide spectrum of chronic liver diseases. At this moment it is not clear whether these findings can be applied unconditionally to specific patient groups such as chronic viral liver disease (Hepatitis B, C) or chronic non-viral liver disease (non-alcoholic fatty liver disease, NAFLD). Using MRE in specific patient groups could provide an accurate and non-invasive tool for diagnosing different stages of liver fibrosis and to monitor treatment response. Moreover, combining MRE with Proton Magnetic Resonance Spectroscopy (1H-MRS) in NAFLD patients could offer a non-invasive way to discriminate between simple steatosis and the more serious condition of non-alcoholic steatohepatitis (NASH), the latter of which is prone to the development of hepatic fibrosis and cirrhosis.

Study objective

To assess the diagnostic accuracy of MR Elastography in detecting and monitoring different degrees of liver fibrosis compared to FibroScan and histopathology in patients with suspected chronic viral liver disease and non-alcoholic fatty liver disease.

Study design

In this single centre, non-randomized prospective study all consecutive, consenting adult patients with suspected chronic viral liver disease and non-alcoholic fatty liver disease from our Gastroenterology department with an indication for liver biopsy will be included.

Study burden and risks

MR Elastography and proton MR Spectroscopy (1H-MRS) will be combined in one MRI session of approximately 60 minutes. Both MRE and 1H-MRS are non-invasive, non-ionizing examinations, during which the patient will have to lie still on his back in a MRI scanner. No contrast medium will be administered. All participating patients will be asked permission to be contacted again for a follow-up MRE/1H-MRS scan. Only consenting patients with proven viral hepatitis

will be included in this follow-up subgroup. This means that participating in the study will require either one or two extra visits to the hospital, depending on the patients* individual diagnosis.
Participating in this study has no direct advantage for the patient, except extra insight in their disease. Patients are not delayed in treatment for their disease. There will be little extra physical and psychological discomfort associated with participation.

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 over 18 years of age;
Patients suspected of chronic viral or chronic non-alcoholic liver disease with an indication for liver biopsy (ASAT elevated >60 mmol/l (n<=40 mmol/l));

Written informed consent

Exclusion criteria

Patients under 18 years of age;
Alcohol consumption of >3 units/day for males and >2 units/day for females;
Patients who are pregnant;
Patients who are claustrophobic (MRI scanner);
Patients who have magnetic or radiofrequency sensitive implants (MRI scanner);
Patients with extreme obesity (MRI scanner)

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):	01-07-2009
Enrollment:	95
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	NL27571.018.09