Validation of 3.0 Tesla 1H-MR Spectroscopy for assessment of liver steatosis in patients with non-alcoholic fatty liver disease and chronically infected hepatitis C

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Validation and quantification of 3.0 Tesla 1H *MRS for the assessment of hepatic steatosis in patients with non alcoholic fatty liver disease and patients chronically infected with hepatitis C. Is there a close correlation between the 1H *MRS...

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

Summary

ID

NL-OMON31271

Source
ToetsingOnline

Brief title
Validation of 3.0 Tesla 1H-MR Spectroscopy for liver steatosis

Condition

- Hepatic and hepatobiliary disorders

Synonym
fatty liver, hepatitis C, jaundice, liversteatosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: 1H-MR Spectroscopy, Hepatitis C, liver steatosis, NAFLD

Outcome measures

Primary outcome

Validation and quantification of hepatic steatosis with 3.0 Tesla 1H-MRS in

patients with non-alcoholic fatty liver disease or chronically infected

hepatitis C and correlation with histological analysis of the liver biopsy and

clinical parameters

Secondary outcome

nvt

Study description

Background summary

Hepatic steatosis is fat accumulation in the liver. Hepatic steatosis is caused by obesitas, diabetes and dyslipidemia, features of the metabolic syndrome. It is estimated to be present in 30% of the western population. 10% of these patients develop a more severe condition called non-alcoholic steatohepatitis (NASH). Due to inflammation NASH eventually can develop into liver cirrhosis. This process is called non-alcoholic fatty liver disease (NAFLD) and is at the moment the most common chronic liver disease. Other causes of hepatic steatosis are: alcohol induced hepatic steatosis, drug induced hepatic steatosis, chronic hepatitis C infection and chemotherapy associated steatohepatitis (CASH). Hepatic steatosis in CHC has a negative impact on treatment efficacy and enhances the progression to fibrosis. Liver biopsy and histological examination has been the reference standard for assessing hepatic steatosis, but major and minor complications and sampling errors because of inhomogeneous distribution of fat in the liver are reported. At the moment there is no suitable non-invasive technique for quantifying hepatic steatosis. Proton Magnetic

Resonance Spectroscopy (1H-MRS) is a safe, non-invasive and repeatable (non-ionizing) diagnostic tool that may allow quantifying various components of fat such as saturated and unsaturated fatty acid chains. This technique is not yet used as a standard clinical tool. We suggest that 3.0 Tesla (due to higher spectral resolution than 1H-MRS at 1.5 Tesla, which provides better insight in various fatty acid chians) 1H -MRS is a suitable and promising candidate for quantitative assessment of hepatic steatosis.

Study objective

Validation and quantification of 3.0 Tesla 1H *MRS for the assessment of hepatic steatosis in patients with non alcoholic fatty liver disease and patients chronically infected with hepatitis C. Is there a close correlation between the 1H *MRS measurement of fat and histological assessment of fat from liver biopsy? Is it possible to validate and quantify 1H *MRS, so it can be used as a viable, repeatable, and non-invasive standard clinical tool for the assessment of hepatic steatosis?

Study design

In this prospective pilot study the population consists of consecutive patients with non-alcoholic fatty liver disease and patients with chronically infected hepatitis C (all genotypes (1-6)) visiting the outpatient clinic of the AMC Liver Center. Those who require a liver biopsy are being asked to participate. After informed consent, patients are referred for 1H-MRS and ultrasonography of the liver consequently followed or preceded by liver biopsy. Histological evaluation of the liver biopsy will be compared to the amount of fat measured by 1H-MRS for validation and correlation studies. Liver biopsy and 1H -MRS will be performed in the same part of the liver.

Study burden and risks

The patients in this study will undergo 1H-MRS, ultrasonography and liver biopsy. Liver biopsy will only be performed when clinically indicated. A liver biopsy is not without harm, with reported major and minor complications rates of 1% and 13.6%, respectively. The most reported complications are bleeding, shoulder pain and biliairy leakage. 1H-MRS is a non-invasive, non-ionizing 45 minute examination in the MRI scanner, which requires one extra visit to the hospital. Blood tests and ultrasonography are indicated for assessing disease progression. Ultrasonography is also a harmless non-invasive, non ionizing examination. No extra bloodtests will be needed. 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 with signs of non-alcoholic fatty liver disease and who require liver biopsy for steatosis assessment
Patients chronically infected with hepatitis C and who require liver biopsy

Exclusion criteria

Patients under 18 years of age
Patients who are pregnant
Hepatitis C patients with HOMA-IR score < 2
Hepatitis C patients with alcohol consumption of > 40 grams per week

Patients who are claustrophobic
Patients who have magnetic or radiofrequency sensitive implants
Patients with extreme obesity (maximum weight limit MRI scanner 140kg)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2007
Enrollment:	60
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	NL18628.018.07