Validation of pre-operative 3.0 Tesla H1-MR spectroscopy for assessment of hepatic steatosis as a risk factor for post-operative outcome after hepatectomy

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Validation of pre-operative H1-MRS at 3.0 Tesla for assessment of hepatic steatosis as a risk factor for postoperative morbidity and mortality after hepatectomy. Is there a close correlation between the 1H -MRS measurement of fat and the...

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

Summary

ID

NL-OMON30877

Source
ToetsingOnline

Brief title
Validation of H1-MR spectroscopy for assessment of hepatic steatosis

Condition

- Hepatic and hepatobiliary disorders

Synonym
fatty liver, Liver steatosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Hepatectomy, Hepatic steatosis, MR spectroscopy

Outcome measures

Primary outcome

Valdation and quantification of hepatic steatosis with 3.0 Tesla 1H*MRS and

correlation with clinical parameters and histological and biochemical analysis

of liver biopsies

Secondary outcome

influence of hepatic steatosis on postoperative morbidity and mortality

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).
On the other hand, steatosis in liver surgery and liver transplantation has been recognized as a serious risk factor for postoperative recovery. Patients undergoing an extended liver resection with a steatosis grade of more than 30% (determined by histological evaluation of liver biopsy) are at high risk for developing postoperative liver failure due to a compromised rest liver function. Similarly, when a liver graft of 30-60% steatosis is being transplanted there is a higher risk of poor functioning after implantation. Preoperative assessment of hepatic steatosis would be desirable to estimate the

patients risk for liver resection surgery. Until now histological examination of a liver biopsy has been the reference standard for invasive assessment of hepatic steatosis, but major and minor complications and sampling errors because of the heterogeneous distribution of fat in the liver are reported. At the moment there are no suitable non-invasive techniques for quantifying hepatic steatosis. Magnetic Resonance Proton Spectroscopy (1H-MRS) seems a viable alternative, repeatable, patient friendly and non invasive, but is not yet used as a standard clinical tool. We suggest that 1H-MRS at 3.0 Tesla can be used for quantitative assessment of hepatic steatosis

Study objective

Validation of pre-operative H1-MRS at 3.0 Tesla for assessment of hepatic steatosis as a risk factor for postoperative morbidity and mortality after hepatectomy.
Is there a close correlation between the 1H -MRS measurement of fat and the histological and biochemical assessment of fat from multiple biopsies taken from the resected part of the liver?
Is it possible to validate and quantify 1H -MRS so it can be used as a viable, repeatable and non-invasive diagnostic tool for the assessment of hepatic steatosis?

Study design

In this prospective pilot study consenting consecutive patients for liver resection (hepatectomy) are recruited by the surgeon and included in the study by 2 research fellows. These patients will have diagnostic liver evaluation by ultrasound, CT and 1H *MRS preoperatively. Within normal timeframe the surgeon will perform a liver resection. Multiple biopsies from the non-tumorous part of the resected liver will be investigated histopathologically and biochemically. This will be compared to the amount of fat measured by 1H *MRS for validation and correlation studies. Also, a possible correlation of different measurements of steatosis with the postoperative recovery up to 3 months will be investigated

Study burden and risks

These patients require a liver resection, which would also have been performed in normal clinical practise. CT scanning and ultrasound is also part of normal clinical pre-operative work-up, as well as blood sampling during pre-operative work-up, during admission and post-operative work-up.
During regular blood sampling at hospital admission one extra blood sample will be taken. 1H-MRS is a non-invasive, non-ionizing 60 minute examination in the MRI scanner, which requires one extra visit to the hospital. Patients are not delayed in surgery for the extra diagnostic 1H-MRS. Biopsies for the evaluation of steatosis will be obtained from the resected non-tumorous part of the liver,

in close consultation with the pathologist. No biopsies from remnant liver are required, so the patient is not opposed to any additional risk. 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 who require a liver resection for:
- hepatocellular carcinoma
- colorectal metastasis
- benign tumors

Exclusion criteria

Patients under 18 years of age
Patients not suitable for surgery in case of co-morbidity
Patients who are pregnant
Patients who require an acute liver resection
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 non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2007
Enrollment:	30
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	NL17294.018.07