Evaluation of the healthy liver using new magnetic resonance imaging and spectroscopy methods at 3.0T and 7.0T

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Primary:- To determine default values of liver phosphorus metabolite ratios using 31P-MRS at 3.0T in healthy volunteers- To determine default values of fractional anisotropy (FA) and apparent diffusion coefficient (ADC) in the liver using DTI-MRI at...

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

Summary

ID

NL-OMON36052

Source
ToetsingOnline

Brief title
31P-MRS @ 3.0T and 7.0T

Condition

- Hepatic and hepatobiliary disorders

Synonym
Non-alcoholic fatty liver disease

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MRI, NADPH, phosphorus, spectroscopy

Outcome measures

Primary outcome

For 31P-MRS: Liver phosphorus metabolite ratios

For DTI-MRI: Apparent Diffusion Coefficient (ADC)-values of the liver;

Fractional Anisotropy (FA)-values of the liver

Secondary outcome

For 31P-MRS: Spectral resolution (line width); Signal to Noise Ratio (SNR); T1

measurements

For 1H-MRS: Liver fat percentage; Identification of individual fat peaks

Study description

Background summary

Hepatic steatosis prevalence is steadily rising, largely due to the obesity epidemic. Non-alcoholic fatty liver disease (NAFLD) can progress from simple steatosis to non-alcoholic steatohepatitis (NASH), fibrosis, cirrhosis and ultimately hepatocellular carcinoma. Importantly, the subgroup of patients with NASH is at the highest risk of disease progression. It is therefore imperative to distinguish the NASH patients from those with simple steatosis. The reference standard for diagnosis is a liver biopsy, which is prone to increased morbidity and mortality, sampling error and large inter- and intraobserver variability. Several imaging techniques are available for the diagnosis and follow-up of NAFLD. Recent publications have renewed interest in phosphorus MR-spectroscopy (31P-MRS). This technique can be used to identify phosphor-containing metabolites, such as ATP and NADPH. The latter plays in important role in fibrosis development and is seen as a marker of inflammatory and especially fibrinogenic activity in the liver. Recent evidence points in the direction of an increase in NAPDH level in NASH, but not in simple steatosis. It could therefore be of use in distinguishing between these two groups. We aim to determine normal values of liver phosphorus metabolite ratios using 31P-MRS measurements at the 3.0T. An increase in a MRI-scanner*s field

strength increases the spectral quality of the spectra it generates, meaning metabolites are identified more easily. This is mainly due to a higher signal-to-noise ratio (SNR). One of the two Dutch 7T MRI scanners is located at the University Medical Center Utrecht. We aim to use this high field strength MRI scanner to perform 31P-MRS with a half-volume coil and compare these results to 31P-MRS using the current standard at a field strength of 3.0T with a surface coil. Lastly, diffusion tensor imaging MRI (DTI-MRI) - a method that images the molecular movement of water - can be used to identify liver fibrosis. The latter is seen in NASH patients, but not in those with simple steatosis. It potentially is another method to distinguish NASH from simple steatosis. We aim to use DTI-MRI to generate ADC- and FA-maps of the liver and determine normal values of these parameters. To assess liver fat percentage we will use proton MR-Spectroscopy (1H-MRS), a validated methodology for this purpose.

Study objective

Primary:
- To determine default values of liver phosphorus metabolite ratios using 31P-MRS at 3.0T in healthy volunteers
- To determine default values of fractional anisotropy (FA) and apparent diffusion coefficient (ADC) in the liver using DTI-MRI at 3.0T in healthy volunteers

Secundary:
- To evaluate the added value of 31P-MRS at 7.0T using a quadrature volume coil compared to the current 31P-MRS standard at 3.0T using a surface coil in healthy volunteers.

Study design

This is a two centre observational study.

Study burden and risks

No substantial risks or benefits are associated with the aforementioned diagnostic procedures. Travel expenses are reimbursed and subjects will receive ¤85.- (2 sessions) or ¤140,- (3 sessions) for time spent. The procedure requires all 30 subjects to visit the AMC Amsterdam twice for two separate MRI-sessions at 3.0T. Furthermore, 10 subjects out of 30 will be asked to visit the UMC Utrecht once for one MRI-scan at 7.0T. The examinations at 3.0T will each take circa 50-60 minutes in the MRI-scanner, while the examination at 7.0T will take circa 40-50 minutes. During the MRI-scans subjects will have to lie still. Alll subjects will be asked to fast 4 hours prior to each MRI-scan, i.e. no eating or drinking except water or tea (without sugar). No contrast agent will be administered. MRI-scans are save non-invasive, non-ionizing

examinations.

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

Healthy volunteers, 18 years or older
Written informed consent

Exclusion criteria

- Healthy volunteers under 18 years of age
- Alcohol consumption of >3 units/day for males and >2 units/day for females (steatogenic

effect)
- Contraindications for MRI (with the use of standard MRI checklist, see document E4)
- Body Mass Index (BMI) >27 (there is a high prevalence of hepatic steatosis in overweight persons)
- Diabetes Mellitus
- History of or current 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, rosiglitazon, methotrexate, antiretroviral therapy, tamoxifen, tetracycline, valproate

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	06-06-2012
Enrollment:	30
Type:	Actual

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	NL36553.018.11