Evaluation of the CAP-value for quantitating liver steatosis using 1H-MRS and liver biopsy as reference standard

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Main objective: investigate the correlation between CAP-values with fat percentages found at 1H-MR Spectroscopy and steatosis grade at liver biopsy. Secondary objectives: investigate the reproducibility of CAP-measurements; investigate the...

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

Summary

ID

NL-OMON41661

Source
ToetsingOnline

Brief title
CAPtivating

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: CAP, Liver, Spectroscopy, Steatosis

Outcome measures

Primary outcome

The correlation between CAP-values and fat percentage found at 1H-MR

Spectroscopy of the right liver lobe and steatosis grade at liver biopsy

Secondary outcome

Inter- and intraobserver variability for CAP-values (at visit 1)

Reproducibility (within-session and within-weeks) for CAP-values (visit 1 and 2)

Correlation between CAP-values and liver viscosity values found at MRE

Correlation between TE-values (FibroScan) and Elastography-values found at MRE

Correlation between CAP-values and fat percentage at MRI-based liver fatmaps

Effect of a standardized amount of fat intake on CAP-values

Perceived burden and patient preference

Study description

Background summary

Hepatic steatosis is becoming a large health burden in both Western and non-Western societies. There is a need for specific diagnostic tools that can both separate patients with significant steatosis from those without and quantify the amount of steatosis. Quantification will help clinicians to guide therapy. Several tools exist, such as ultrasonography, CT, serum test panels, MR Imaging, 1H-MR Spectroscopy and liver biopsy. However, all suffer from shortcomings. A new tool for quantifying steatosis is the Controlled Attenuation Parameter (CAP), available on the FibroScan© (a device used to determine the presence of liver fibrosis with ultrasound waves and vibrations). This tool gives a continuous outcome measure and has thus far been evaluated mainly against semi-quantitative scoring of liver biopsies and not against other continuous outcome measures such as 1H-MR Spectroscopy or MRI based liver

fat-maps. We hypothesize that CAP-values correlate with fat percentages found at 1H-MR Spectroscopy and that CAP-values can be used in daily practice for reproducible and accurate fat measurements.

Study objective

Main objective: investigate the correlation between CAP-values with fat percentages found at 1H-MR Spectroscopy and steatosis grade at liver biopsy. Secondary objectives: investigate the reproducibility of CAP-measurements; investigate the correlation between FibroScan (CAP-value and TE-value) and MR Elastography (Viscosity and Elastography parameters); investigate the correlation between CAP-values and fat percentage at MRI-based liver fatmaps; investigate and compare the burden of and patient preference for liver biopsy, CAP-measurement and MRI-scan for liver fat measurements; investigate the influence of a fatty meal on CAP-values in healthy volunteers.

Study design

Multi-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 technique (CAP-value) when it is to be used in clinical practise. In the future, patients with chronic liver disease may benefit considerably by this new diagnostic modality. FibroScan© is a rapid, non-invasive measurement using a hand-held ultrasound device that sends a vibration into the tissue of interest, in this case the liver. It is a safe tool. FibroScan© sessions will take approximately 10 minutes, depending on whether one or two examiners are present. 1H-MR Spectroscopy and MRE will be performed during one or two MRI sessions of approximately 30-45 minutes. MRI 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 in a tunnel. Subjects will have to hold their breaths several times on expiration. Subjects can indicate when they are ready for the next breath hold. From experience, they 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 (maximum of two) to the hospital. No oral or intravenous contrast medium will be given to the patient. Subjects with contra-indications for MRI-scanning are excluded from participation in this study (see appendix E4). Subjects are not delayed in treatment for their disease as those requiring as those requiring (change in) medication following the result of liver biopsy are excluded. Administration of the Calogen Neutral (dietary supplement drink) to subjects in cohort B will temporarily raise subjects* triglycerides, but will have no temporary or lasting ill effects on subjects* health.

Additionally, 7 * 10ml blood will be drawn via venepuncture in cohort B only.
All subjects will be asked to fast overnight or for at least 8 hours before measurements.

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:
- 18 years or older
- Liver biopsy performed within 6 weeks of visit 1
- FibroScan examination possible with M-probe
- Written, informed consent;Healty volunteers:
- 18 years or older
- No history of liver disease

- FibroScan examination possible with M-probe
- Written informed consent

Exclusion criteria

For all subjects:
- Alcohol consumption of >3 units per day for male and >2 units per day for females
- Focal liver lesion(s) in the right liver lobe (proven with histology results or imaging)
- Contra-indications for MRI scanning (except cohort B)
- Start of or change in treatment of liver disease less than 4 weeks before visit 1 or liver biopsy (whichever comes first) or - for the subset of cohort A - in between visit 1 and 2
- Start of or change in use of medications known to have steatogenic effects on the liver (synthetic oestrogens, corticosteroids, diltiazem, nifedipine, perhexilline, amiodarone, metformin, insulin, statins, rosiglitazon, methotrexate, antiretroviral therapy, tamoxifen, tetracycline, valproate* less than 4 weeks before measurements or - for the subset of cohort A - in between visit 1 and visit 2
- Known hemochromatosis;For healthy volunteers:
- CAP-value of 300 or more (measured as part of screening visit after informed consent)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-03-2013
Enrollment:	78
Type:	Actual

Ethics review

Approved WMO Date:	04-12-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-01-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-07-2013
Application type:	Amendment
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

ID: 23759
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL41865.018.12
OMON	NL-OMON23759
OMON	NL-OMON25092