Evaluation of the CAP-value for quantitating liver steatosis in obese children using 1H-MRS as reference standard

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To investigate the correlation between the CAP-value measured with the FibroScan® device and liver fat percentage measured with 1H-MRS in a well-characterized cohort of obese children at risk of having fatty liver disease.

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

Summary

ID

NL-OMON44182

Source
ToetsingOnline

Brief title
CAPped

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, Paediatric, Spectroscopy, Steatosis

Outcome measures

Primary outcome

Correlation between CAP-values and fat percentage found at 1H-MR Spectroscopy

of the right liver lobe (segment VI or VII).

Secondary outcome

Inter- and intraobserver variability for CAP-values

Success rate of CAP-measurements

Correlation between TE-values (measured with FibroScan®) and liver stiffness

values (measured with MRE)

Correlation between CAP-values (measured with FibroScan®) and fat percentage at

MRI-based liver fatmaps

Diagnostic accuracies of CAP-value and US

Study description

Background summary

The number of overweight childeren in The Netherlands is growing rapidly, causing a rise in the number of children with fatty livers. However, not all overweight children will develop fatty livers. Currently, there are no easy, cheap and non-invasive methods to establish which child does and which child does not have fatty liver disease. As fatty liver disease (or hepatic steatosis) is toxic for the liver and increases the risk of developing type 2 diabetes and cardiovascular disease, such easy, cheap and non-invasive methods are subject of many investigations.

The current best practice for establishing the presence of fatty liver disease

is liver biopsy, which is seldomly performed in the paediatric population due to its concomitant risks (bleeding, pain, morbididty and even mortality). Our center (AMC Amsterdam) has ample experience with MRI-methods that allow measurement of the liver fat percentage in either children of adults. MRI-scans are much more patient friendly than liver biopsy but still not all subjects are capable of having MRI-scan (they may be claustrophobic, or too large to fit the MRI-scanner). Furthermore, the costs of MRI-scans makes this less attractive as screening tool for the presence of fatty liver disease.

In this study we aim to investigate a new method for liver fat assessment in (overweight) children at risk of developing fatty liver disease. This method uses the FibroScan® devive (a special ultrasonography device that hitherto only measured liver elasticity) to measure the CAP-value. It takes about 5 minutes, is easy and does not cause discomfort to the patient. The CAP-value is a quantitative measure of the amount of liver fat. In this study we will investigate the reliability and accuracy of the CAP-value by comparing its results with the liver fat percentage as measured with MRI. As US is still the mainstay tool for most paediatricians and (paediatric) radiologists, a head-to-head comparison of the performance of US and FibroScan/CAP with 1H-MRS as reference is important and also a secondary outcome measure.

Study objective

To investigate the correlation between the CAP-value measured with the FibroScan® device and liver fat percentage measured with 1H-MRS in a well-characterized cohort of obese children at risk of having fatty liver disease.

Study design

An observational study in 60 patients recruited from the department of Paediatrics of the AMC, Slotervaartziekenhuis, VUmc, Onze Lieve Vrouwe Gasthuis and Ziekenhuis Amstelland) with an increased risk of having fatty livers. All 60 subjects will receive a FibroScan® /CAP-measurement, US and MRI-scan (1H-MR Spectroscopy, liver fatmapping, MRE) for liver fat percentage on 1 day performed in a single centre (AMC). By comparing both results, we will test whether CAP-value can be used in clinical practice as a quantitative liver fat measurement in children.

Study burden and risks

The advantage of participation in this study for patients is that presence of liver steatosis is very accurately determined by 1H MRS. Liver steatosis is a well established risk factor in obesity related to increased risk for diabetes type 2. It thus helps in risk stratifying in obesity. In addition, the results of the extended MRI scan and FibroScan®/CAP are discussed in detail with the

parents/patients by the consulting paediatrician. Furthermore, it is important to evaluate this new technique (CAP-value) to ascertain whether it already can be used for obese children in clinical practise. In the future, obese children and children 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 and the vibration causes no discomfort. The transient elastography (TE) value gives information on liver stiffness (fibrosis) while the new CAP-value provides information on the amount of fat. FibroScan®/CAP and US sessions will take approximately 10 minutes (3 complete measurements). 1H-MR Spectroscopy , liver fatmapping and MRE (for liver stiffness measurements) will require a total in-room time of at most 30 minutes. MRI is a non-invasive, non-ionizing examination. During scanning the patient will have to lie still on his or her back in a tunnel. Subjects will also have to hold their breaths several times on expiration. From experience, they do not find it hard to follow and perform these instructions. In fact, we expect that children will find the MRI-scans less boring when performed with breath hold procedures as they report that lying still during MRI-scans is the most bothersome aspect of having MRI performed.

The vibrations of the MRE transducer are felt, but do not cause discomfort or pain. The physical burden of this examination is therefore very limited. Participation in the study will require one extra visit to the hospital. No oral or intravenous contrast medium will be given to the subjects. Subjects with contra-indications for MRI-scanning are excluded from participation in this study (see appendix E4). There will be little extra physical and psychological discomfort associated with participation besides the four hour fast period.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Written, informed consent from parent(s) and subject (when *12 years of age);For current patients:
- Clinically suspected or high risk profile of hepatic steatosis based on at least one of the following:
- abnormal echogenicity of liver in ultrasonography (performed during routine clinical work-up, i.e. not during or as part of the study);
- elevated serum transaminases levels;
- high BMI (>+3 z-score) and/or waist circumference (>95 percentile);
- insulin resistance.;For patients no longer in active follow-up:
- Liver steatosis detected during follow-up in this clinic in the last 3 years:
- Based on the same criteria as above and/or;
- Liver biopsy;
- MRI

Exclusion criteria

- Age <8 and *18 years of age
- The need for sedation or anaesthesia during the MRI examination.
- General contra-indications for MRI scanning
- Known focal liver lesion(s) in the right liver lobe
- Known concomitant liver disorders

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):	06-10-2014
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	04-06-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	12-01-2017
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: 28273
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL47936.018.14
OMON	NL-OMON28273