Patient friendly liver fat measurements (CAP) in children with obesity compared with MRI-determined liver fat percentage.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON28273

Source
Nationaal Trial Register

Brief title
CAPped

Health condition

Non-Alcoholic Steatohepatitis (NASH), Non-Alcoholic Fatty Liver Disease (NAFLD), Obesity, Paediatrics, Hepatic Steatosis, FibroScan, 1H-MR Spectroscopy Proton Density Fat Fraction (MRS-PDFF)

Sponsors and support

Primary sponsor: Amsterdam UMC, location AMC, Department of Radiology & Nuclear Medicine
Source(s) of monetary or material Support: Amsterdam UMC, location AMC, Department of Radiology & Nuclear Medicine

Intervention

Outcome measures

Primary outcome

Diagnostic accuracies of CAP and US for the detection of hepatic steatosis using 1H-MR Spectroscopy derived proton density fat fraction (MRS-PDFF) as reference standard.

Secondary outcome

1. Inter- and intraobserver variability for CAP-values;
2. Success rate of CAP-measurements;
3. Correlation between CAP-values and fat percentage at MRI-based liver fatmaps.

Study description

Background summary

CAPped is a study that compares the diagnostic accuracy of the controlled attenuation parameter (CAP) and ultrasonography (US) to detect hepatic steatosis in an overweight or obese paediatric population in the Netherlands using MRI-determined liver fat fractions as reference standard. Sixty subjects will be included and receive CAP, US and a MRI-scan, preferably on one day. All subjects are recruited in the Netherlands (with all study procedures performed in a single centre).

Study objective

Hepatic steatosis is becoming a large health burden in both Western and non-Western societies. In children, the trend of increasing obesity means more and more children are at risk of developing liver steatosis. As liver steatosis is a risk factor in the development of diabetes mellitus type 2 and cardio-vascular disease, there is a need for specific diagnostic tools that can identify the children with liver steatosis and if possible, quantify the amount of steatosis. Quantification will help clinicians to guide therapy. Several tools exist, such as ultrasonography (US), 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). This tool has been investigated in adults thus far and has only been compared to the results of liver biopsy, a semi-quantitative score. In this study we will investigate our hypothesis that the Fibroscan/CAP can be used in obese children to identify those with steatosis and obtain a quantitative measure of the amount of liver fat and that its diagnostic accuracy is higher than of US.

Study design

1. CAP-value measured with FibroScan device (at least once by examiner 1, time and schedule permitting twice by a second examiner), US and (availability pertaining) MRI at visit 1.
2. Depending on scanner availability, MRI was performed on a second visit in short proximity to visit 1.

Intervention

N/A

Contacts

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Eligibility criteria

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;
- 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

Exclusion criteria

- Age <8 and >18 years
- The need for anaesthesia during the MRI examination.
- General contra-indications for MRI scanning (use of MRI checklist, see document E4)
- Known focal liver lesion(s) in the right liver lobe (proven with histology results or imaging)
- Known concomitant liver disorders

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	60
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	21-01-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44182
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL4155
NTR-old	NTR4345
CCMO	NL47936.018.14
OMON	NL-OMON44182

Study results

Summary results
N/A