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

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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...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28273

Bron
Nationaal Trial Register

Verkorte titel
CAPped

Aandoening

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

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC, Department of Radiology & Nuclear Medicine
Overige ondersteuning: Amsterdam UMC, location AMC, Department of Radiology & Nuclear Medicine

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2014
Aantal proefpersonen:	60
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	21-01-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44182
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A