Measuring hepatic steatosis with ultrasound and MRS in children with overweight or obesity

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The aim of this study is to validate the ultrasonographic hepatorenal index in children with overweight, obesity and morbid obesity, by using MRS.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON54724

Source
ToetsingOnline

Brief title
Hepatic steatosis in children with overweight

Condition

- Other condition
- Hepatic and hepatobiliary disorders

Synonym
fatty liver disease, Non-alcoholic fatty liver disease

Health condition

Obesitas

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Childhood obesity, Hepatic steatosis

Outcome measures

Primary outcome

Ultrasonographic hepato-renal index and liver fat percentage as determined by magnetic resonance spectroscopy.

Secondary outcome

Metabolic and anthropometric parameters, to correlate with the measured liver parameters (for example waist-circumference, lipids, blood pressure and glucose metabolism). The goal is to gain more insight into which children can be identified as being at-risk for developing NAFLD based on their cardiometbolic profile.

Study description

Background summary

Obesity is associated with a variety of co-morbidities. Children with obesity are more likely to have risk factors associated with cardiovascular disease (eg, hypertension, high cholesterol, and type 2 diabetes mellitus), but also non-alcoholic fatty liver disease (NAFLD). A recent meta-analysis has shown that the prevalence of NAFLD in obese pediatric populations is approximately 35%, compared to approximately 8% in general pediatric populations, making it a very important health threat in these populations. The golden standard for the diagnosis of NAFLD is liver biopsy. However, since liver biopsy is associated with a certain risk of morbidity and mortality, this method is inappropriate for screening large populations at-risk for developing NAFLD. Magnetic resonance spectroscopy has demonstrated excellent correlation with liver biopsy

and the most accurate non-invasive method to measure liver fat content in children. However, MRS is an expensive method that is not available in all centers. A novel ultrasonographic measurement to quantitatively assess liver steatosis is the hepatorenal index (HRI), which is calculated as the ratio of hepatic and renal ultrasonographic brightness. Previous studies in adults have shown a high sensitivity and specificity of the HRI, as compared to liver biopsy as well as H-MRS. However, the measurement of the HRI has never been validated in children. The validation of this simple, non-invasive method to quantitatively assess fat accumulation in the liver, could improve the screening for, and follow-up of, NAFLD in at-risk populations.

Study objective

The aim of this study is to validate the ultrasonographic hepatorenal index in children with overweight, obesity and morbid obesity, by using MRS.

Study design

Cross-sectional study.

Study burden and risks

MRS is a safe measurement, as long as none of the before mentioned exclusion criteria are met. Measurements performed during the study could potentially lead to unexpected medical findings. If the subject does not want to be informed about incidental findings, he/she cannot participate in the study. Lying in the MR scanner can cause some discomfort, since children have to lie still for about 45 minutes.
In adults, the HRI has shown to be an easy, reproducible method to quantitatively measure liver fat accumulation, with a high sensitivity and specificity (compared to liver biopsy and MRS). However, the (validity) of the HRI has never been studied in children. Therefore, it is unknown if this method is also reliable in pediatric populations. Also cut-off points for children are unknown.

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

· Participation in the COACH program
· Aged below 18 years

Exclusion criteria

· Steatosis on liver ultrasonography
· Elevated liver transaminase levels above two times the upper limit of normal (>44 U/L for girls and > 52 U/L for boys)
· Implanted medical devices such as pacemakers or neurostimulators
· Metal objects in the body (for instances prosthetics, piercings, metal parts in the eye, permanent eyeliner)
· Previous brain surgery
· Cardiac arrhythmia
· Epilepsy
· Claustrofobia
· Not wanting to be informed about accidental findings on MRS

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-08-2020
Enrollment:	54
Type:	Actual

Ethics review

Approved WMO Date:	27-08-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO Date:	15-04-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL64534.068.18