Non-alcoholic fatty liver disease in obese children: long-term effects of a lifestyle intervention. Follow-up study of a cohort

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To determine the 1 year sustainability of the effects of a lifestyle intervention on NAFLD in severely obese children and determine the relation between long term changes in liver steatosis and other clinical and biochemical parameters. Finally, to...

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

Summary

ID

NL-OMON32646

Source
ToetsingOnline

Brief title
NAFLD in children: follow-up study

Condition

- Hepatic and hepatobiliary disorders
- Lipid metabolism disorders

Synonym
non-alcoholic fatty liver disease; fatty liver

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Van de Broek Lohman fonds

Intervention

Keyword: 1-Non-alcoholic fatty liver disease (NAFLD), 2- Magnetic Resonance Spectroscopy, 3- Obesity, 4- Children

Outcome measures

Primary outcome

Change in percentage of liver steatosis between end of treatment in previous

study and one year later.

Secondary outcome

Correlation between change in liver steatosis and changes in a panel of risk

factors.

Change in status of carotid atherosclerosis between start of treatment in

previous study and one year later and correlation with change in the perentage

of liver steatosis.

Study description

Background summary

In February 2008, a study protocol titled *Non-alcoholic fatty liver disease in obese children: measuring liver steatosis by MR Spectroscopy* (MEC number 07/141) was started. In that study, 50 children with non-alcoholic fatty liver disease (NAFLD) are being identified from a cohort of severely obese children and the effects of 6 months of lifestyle intervention on NAFLD are evaluated. Proton magnetic resonance spectroscopy (1H-MRS) is used in that study to non-invasively and accurately measure liver steatosis.
Even more important than short term effects is the sustainability of the effects of lifestyle interventions on NAFLD. In the presently proposed follow-up study protocol, the sustainability of the effects of lifestyle interventions on NAFLD are investigated. Only one paediatric study into the long term efficacy has been published. In that study, ultrasonography and serum transaminases are used which are inaccurate diagnostic tools to determine NAFLD.

Study objective

To determine the 1 year sustainability of the effects of a lifestyle intervention on NAFLD in severely obese children and determine the relation between long term changes in liver steatosis and other clinical and biochemical parameters. Finally, to determine whether long term changes in liver steatosis are related to changes in signs of atherosclerosis.

Study design

In a previously identified cohort of obese children with NAFLD, we will measure liver steatosis using 1H-MRS, measure body fat distribution using conventional MR imaging, perform ultrasound of the carotid arteries for signs of arthrosclerosis and collect clinical and biochemical data one year after these children participated in a lifestyle intervention program.

Study burden and risks

Participants in this study have all been identified as suffering from NAFLD in the previous study. It is standard clinical care that NAFLD is followed up by imaging and blood sampling every 6-12 months in order to identify deterioration of liver function. In the previous study permission was asked to contact patients for future studies. When a patient is included in the study all examinations will be performed during one visit to the AMC hospital. 1H-MRS and MR body fat distribution imaging together is a non-invasive, non-ionizing 30 minute examination in the MRI scanner. Ultrasound of carotid arteries takes about 15-20 minutes and is safe, non-invasive, and subject friendly. Blood sampling will be performed after an overnight fast. History taking and physical examination will take place in the paediatric outpatient clinic of the AMC hospital and will take 15 minutes.

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

- Presence of NAFLD determined by 1H-MRS before treatment
- Completion of at least 2 months of life style intervention at Heideheuvel institute
- Liver fat determined by 1H-MRS after treatment

Exclusion criteria

Other liver disease
Significant alcohol consumption
Use of steatogenic drugs

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	45
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL29337.018.09