The natural history of Non-alcoholic Fatty Liver Disease in obese children: a long-term follow-up study.

Published: 21-08-2018
Last updated: 11-04-2024

To investigate the natural history of NAFLD, we will determine the change in ELF test for fibrosis and change in liver fat percentage measured by 1H-MRS.

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

Summary

ID

NL-OMON48932

Source
ToetsingOnline

Brief title
Fatty Liver Study

Condition

- Hepatic and hepatobiliary disorders

Synonym
Fatty Liver Disease, hepatic 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: Fibrosis, Natural history, Non-alcoholic fatty liver disease, Steatosis

Outcome measures

Primary outcome

- Change in ELF test compared to the measurement performed at the end of the lifestyle intervention in the previous study.

- Change in percentage of liver steatosis measured by 1H-MRS compared to the measurement performed at the end of the lifestyle intervention in the previous study.

Secondary outcome

* Difference in proportion of subjects with steatosis (defined as fat percentage > 1.8%) at the end of the lifestyle intervention and at 6-10 years follow-up.

* Change in co-variables including insulin resistance, glucose, serum ALT level, HDL- and LDL-cholesterol.

* Association between change of steatosis and (change in) several parameters: sex, BMI, age corrected SD score, waist circumference, levels of serum alanine aminotransferase and insulin sensitivity index (HOMA).

* Association between microalbuminuria and NAFLD (steatosis and fibrosis)

Study description

Background summary

Non-alcoholic Fatty Liver Disease (NAFLD) is defined as chronic hepatic steatosis that is not caused by a metabolic/genetic disease, infections, use of

steatogenic drugs, alcoholic consumption or malnutrition. The spectrum of NAFLD ranges from simple steatosis, steatohepatitis, to fibrosis and cirrhosis. Symptoms will usually be absent until complications like decompensated cirrhosis, liver failure or hepatocellular carcinoma occur.
In children the reported pooled prevalence of NAFLD in general population studies is 8% and 34% in studies based on child obesity clinics. However, advanced fibrosis is reported in up to 17% of children referred to liver centres after screening. In view of their long life expectancy, those with significant fibrosis at paediatric age are considered particularly at risk of cirrhosis and its complications during their life time. NAFLD is not only a liver disorder, but also an independent risk factor for type 2 diabetes and probably also for cardiovascular disease and nephropathy at adult age.

The high prevalence and important long term health risks makes NAFLD highly suitable for screening. Current guidelines differ in their advise on the frequency of screening and the follow-up of patients. This is due to limited data on the prevalence and progression of liver fibrosis in paediatric NAFLD patients. Therefore guidelines are mostly based on expert opinion. An evidence based guideline is urgently needed to identify patients with NAFLD and fibrosis in time and thereby offer them adequate treatment and follow-up.

Study objective

To investigate the natural history of NAFLD, we will determine the change in ELF test for fibrosis and change in liver fat percentage measured by 1H-MRS.

Study design

A long term follow-up study.

Study burden and risks

MRI-scans do not involve ionizing radiation and inherent risks are therefore low. As no intravenous contrast is used, there are no risks from contrast-induced-nephropathy or IV-leakage. Claustrophobia can occur, but this is unlikely given the new wide-bore 3T MR Scanner at the AMC that additionally allow subjects to watch TV during the examination. FibroScan is a safe ultrasound-based method to detect steatosis and fibrosis and is already used in clinical practice. The measurement takes 5-10 minutes and is not painful. FibroScan does not involve ionizing radiation.
As such, no structural risk analysis was performed, as the registered product is used within its indication and inherent risks in this measurement are considered low. Venepuncture is a safe method but can sometimes cause mild discomfort. We conclude that participation does not form any health risk for the subjects and that the psysical burden is minimal.
Some of the participants in this follow-up study have been identified as

suffering from NAFLD in the previous study. It is standard clinical care that NAFLD is followed up by imaging (usually ultrasonography) and blood sampling every 6-12 months in order to identify deterioration of liver function. By participating in this study, steatosis can be assessed more accurately since 1H-MRS has a higher accuracy in detecting steatosis compared to ultrasonography. In addition, participants will undergo screening for fibrosis (ELF test and FibroScan) and will be referred to the NAFLD outpatient clinic when signs of fibrosis are present. Subjects who did not have NAFLD at baseline or who showed remission of NAFLD after lifestyle intervention are still at risk of recurrence of steatosis if obesity or other risk factors are still present. The advantage of participation for those patients is that NAFLD is accurately detected and they will receive proper follow-up or treatment if NAFLD is indeed present.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

All patients who participated in the original study will be contacted.

Exclusion criteria

- Other liver disease (viral/autoimmune hepatitis, M. Wilson, haemochromatosis, alfa1-antitrypsine deficiency)
- Metabolic disease (beta-oxidation defects, urea cyclus defects)
- Use of steatogenic medication
- Alcohol consumption > 140 g/week
- Jejuno-ileal surgery
- History of parenteral feeding

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2018
Enrollment:	79
Type:	Actual

Ethics review

Approved WMO

Date:	21-08-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	08-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-06-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL66187.018.18