Non-Alcoholic Fatty Liver Disease in children: determining the prevalence of liver fibrosis using FibroScan®

Published: 25-01-2018
Last updated: 17-01-2025

1) determine the percentage of children with probable significant fibrosis (F>=2) using FibroScan®, when screening children based on the NASPGHAN 2017 guideline.2) determine the cost-effectiveness of screening for NAFLD when following the...

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

Summary

ID

NL-OMON55751

Source
ToetsingOnline

Brief title
Fibrokids

Condition

- Hepatic and hepatobiliary disorders

Synonym
fatty liver, 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, Non-alcoholic Fatty Liver Disease, Non-invasive methods, Screening

Outcome measures

Primary outcome

1) Percentage of children with probable significant fibrosis (FibroScan® value > 7.4 kPa) when screening children based on the NASPGHAN 2017 guideline.

2) Costs of screening to find one patient with significant fibrosis.

3) - Success rate of FibroScan® measurements of M-probe and XL-probe in subjects in who XL-probe, or both XL- and M-probe is indicated by the FibroScan® apparatus.

- Correlation between FibroScan® values of M-probe and XL-probe in subjects in who XL-probe, or both XL- and M-probe is indicated by the FibroScan® apparatus.

- Difference in percentage positive and negative results for significant fibrosis (FibroSscan® value >/<7.4 Kpa) when using M-probe or XL-probe.

- Correlation between ELF test and FibroScan® values (M-probe)

- Correlation between shear wave elastography, FibroScan® (M-probe) and ELF test

- Difference in percentage positive and negative results for significant fibrosis of ELF test (>/< 10.18) compared to FibroScan® M-probe (>/<7.4 kPa).

5) Difference in quality of life between children with NAFLD and healthy children and impact of fibrosis on quality of life.

6) Patient experience during screening process and illness perception

Secondary outcome

Nvt

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 at adult age. The high prevalence and important long term health risks makes NAFLD highly suitable for screening.
Screening for NAFLD in children with obesity is propagated in all major national and international obesity and hepatology guidelines. Screening consists of detecting NAFLD, i.e. liver steatosis, and subsequent detecting the presence of fibrosis, since those with fibrosis are at highest risk of liver and non-liver morbidity and mortality. However, screening for NAFLD is not straightforward due to several gaps of knowledge, most importantly:
- non-invasive tools to subsequently measure liver fibrosis have not been evaluated in a screening setting
- there is limited data on the prevalence and progression of liver fibrosis in paediatric NAFLD
- there is a lack of data on the cost-effectiveness of screening in children
Due to these gaps of knowledge, guidelines are mostly based on expert opinion and do not provide a comprehensive algorithm on when and how to stage fibrosis. Consequently, although screening is widely performed in clinical practice, physicians use different primary screening tools, do not know which screening result should prompt referral and often do not refer patients, when referred staging for fibrosis of those with abnormal screening test is often not performed.Therefore, at present those with relevant liver fibrosis are not adequately identified and denied follow-up and treatment by intensified life

style intervention. The urgency to come to a more comprehensive screening strategy is further underscored by the development of additional pharmacological therapies for NAFLD. These therapies are likely to become available in the near future and will make advanced NAFLD a more easily treatable disorder.

Study objective

1) determine the percentage of children with probable significant fibrosis (F>=2) using FibroScan®, when screening children based on the NASPGHAN 2017 guideline.
2) determine the cost-effectiveness of screening for NAFLD when following the NASPGHAN 2017 screening guideline.
3) investigate the usefulness of two additional non-invasive fibrosis tests;
- XL-probe versus M-probe of FibroScan®
- ELF-test versus FibroScan® (M-probe)
- Shear wave elastography versus FibroScan® (M-probe) and ELF test
4) Quality of life in children with NAFLD
5) Patient experience of screening process and illness perception

Study design

This is a prospective study.

Study burden and risks

FibroScan® is a rapid, non-invasive measurement using a hand-held ultrasound device that sends a vibration into the tissue of interest, in this case the liver. It is a safe tool and the vibration causes no discomfort. For this study, the FibroScan® measurement will be performed with one extra probe (XL-probe). Therefore the measurement will take an additional 5 minutes. We consider this as no extra burden of the participants. Shear wave elastography is a modality that is incorporated in a regular ultrasound apparatus. This measurement will take 5 minutes and causes no discomfort. Venepuncture is part of standard clinical care. For this study 15 ml extra blood will be drawn during the standard venepuncture. Therefore we conclude that there will be little extra physical discomfort with participation.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9

Amsterdam 1100DD
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1100DD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

• Age 8 - 18 years
• Obesity (BMI >= 95th percentile) or overweight (BMI >= 85th and < 94th percentile) with one of the following additional risk factors: central adiposity, insulin resistance, prediabetes or diabetes, dyslipidemia, sleep apnea, or family history of NAFLD/NASH.

Exclusion criteria

• Age > 18 years
• Other liver disease (viral/autoimmune hepatitis, M. Wilson, haemochromatosis, alfa1-antitrypsine deficiency)
• Metabolic disease (beta-oxidation defects, urea cyclus defects)
• Alcohol consumption > 140 g/week
• Use of steatogenic medication

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):	02-02-2018
Enrollment:	604
Type:	Actual

Ethics review

Approved WMO

Date:	25-01-2018
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	20-11-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	23-10-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	03-01-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	29-10-2020
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	NL63812.018.17