Liver Fibrosis in a Home Parenteral Nutrition Cohort

Published: 01-09-2017
Last updated: 12-04-2024

main objective: Investigate the prevalence of liver fibrosis according to TE values in children enrolled in a HPN-program. Secondary objectives: Investigate the correlation between TE values and ELF test score and APRI in children enrolled in a HPN-...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON44440

Source
ToetsingOnline

Brief title
Fibrosis in a HPN cohort

Condition

- Other condition
- Gastrointestinal conditions NEC
- Hepatic and hepatobiliary disorders

Synonym
Intestinal Failure Associated Liver Disease (IFALD), TPN associated liver disease

Health condition

Intestinaal Falen (verschillende onderliggende oorzaken mogelijk bijvoorbeeld: Short Bowel, Passagestoornissen, Microvili inclusieziekte)

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Intestinal Failure Associated Liver Disease (IFALD), Paediatric Home Parenteral Nutrition (HPN) Program, Transient Elastography (Fibroscan)

Outcome measures

Primary outcome

Prevalence of fibrosis according to Transient Elastography (TE).

Secondary outcome

- Correlation between TE values and ELF test score and APRI.

- Correlation between TE values and standard laboratory liver parameters such

as AP, GGT, Bilirubin and transaminases.

- Correlation between TE values and known risk factors for the development of

IFALD.

Study description

Background summary

Intestinal failure-associated liver disease (IFALD) is the most prevalent complication affecting children with intestinal failure receiving (long-term) home parenteral nutrition (HPN). This heterogeneous disease can in it severest form progress to end-stage liver failure requiring liver transplantation. A lot of different definitions exist of this disease and up to now there is no consensus on how it best be diagnosed. Since the presence and severity of IFALD define treatment options (i.e. . type of lipid emulsion (LE) to infuse) defining the presence and severity of IFALD is important. The current reference standard for assessing the presence and severity of IFALD is liver biopsy, this is a procedure with possible serious complications such as bleeding. New diagnostic test to assess the severity of liver disease, Fibroscan*/Transient Elastography(TE) and the Enhanced Liver Fibrosis (ELF) test score, could

provide a solution. Since these tests are non-invasive they could provide a safe alternative. These tests have not been extensively tested in a cohort of patients receiving long term parenteral nutrition. In this study we will investigate our hypothesis that the Fibroscan*/TE can be used in children with intestinal failure receiving long term parenteral nutrition to identify those with IFALD and give a quantitative measure of the severity of fibrosis present.

Study objective

main objective: Investigate the prevalence of liver fibrosis according to TE values in children enrolled in a HPN-program. Secondary objectives: Investigate the correlation between TE values and ELF test score and APRI in children enrolled in a HPN-program; Investigate the correlation between TE values and standard laboratory liver parameters in children enrolled in a HPN-program; Investigate the correlation between TE values and known risk factors for the development of IFALD in children enrolled in a HPN-program.

Study design

This cross-sectional study features one prospective cohort.

Study burden and risks

Participation entails that subjects do not need to visit the AMC an extra time. Instead, the informed consent form is signed by parents and children *12 years of age is signed directly after their outpatient clinic consult. After this the measurements are performed (Fibroscan*/TE). As per usual after this the subjects are referred to the outpatient laboratory of the AMC were blood will be drawn. An extra vial of blood, containing 200µl (2,0ml) of serum will be drawn where the ELF-test will be performed on. No extra venous puncture will be performed for the sake of this study. Fibroscan*/TE measurement takes approximately 5-10 minutes of time. There is some advantage for patients that participate in this study. The data obtained from the FibroScan®/TE measurement will give a better indication than traditional parameters on the presence of liver fibrosis.The results of the Fibroscan*/TE and ELF-test measurement will be extensively discussed by their consulting paediatrician. No incentive is offered for participation in this study.

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

* Written informed consent from parent(s)/caregiver(s) and if applicable subject (when *12 years of age)
* Must be enrolled in the HPN-programme of the ECH-AMC.
* Must receive HPN for at least 3 months continuously.

Exclusion criteria

* Age <3 months and *18 years
* Children with ascites present.
* Children who at the time of outpatient visit have been admitted up to two weeks prior of the outpatient visit due to an episode of septicaemia.
* Children who have not been fasting 3 hours before the measurement of liver stiffness.
* Children who are currently using known hepatotoxic medication other than the total parenteral nutrition formula that is prescribed by the HPN team.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-11-2017
Enrollment:	31
Type:	Actual

Ethics review

Approved WMO

Date:	01-09-2017
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	NL62525.018.17