Non-invasive measurement of hepatic fibrosis in children with cystic fibrosis

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Primary objectivel: assessment of liver fibrose in children with cystic fibrosis, using transient elastography (Fibroscan). Results will be compared with other surrogate markers of CFRLD: liver ultrasonography and biochemical markers: AST, ALT, PT,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal signs and symptoms
Study type	Observational non invasive

Summary

ID

NL-OMON31157

Source
ToetsingOnline

Brief title
Liverfibrosis measurement in CF children

Condition

- Gastrointestinal signs and symptoms

Synonym
liver fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CF, children, fibroscan, liverfibrosis

Outcome measures

Primary outcome

Primary study outcome: liver-elasticity (as measured by Fibroscan): in kPA, related to: ultrasonography of the liver (liver parenchyma, intra- and extrahepatic biliary tree, portal vein, presence of collateral circulation, splenomegaly, flow direction in portal vein) , and related to biochemical markers: cholestasis (elevated blirubin, gamma-GT, alkaline phosphatase) or hepatitis (elevated serum transaminase levels). and liver function tests: prothrombin time, albumin.

Secondary outcome

CFTR mutation, pulmonary function (FEV1), nutritional status, pancreas insufficientie

Study description

Background summary

Patients with cystic fibrosis can develop liver disease. CF related liver disease (CFRLD). CFRLD consists of progressive fibrosis and focal cirrhosis. Fibrosis develops already in the first 10 years after diagnosis. CFRLD is seen in 18 - 37 % of CF patients.
The detection of (early) fibrosis is important, because early treatment with ursodeoxycholic acid (UDCA) can be considered. Liver biopsy is another technique to evaluate fibrosis of the liver. A liver biopsy is an invasive technique, and because of the focal nature of the fibrosis, biopsies can be false-negative. Conventional ultrasonography is not accurate enough to detect early fibrosis.
Transient elastography (Fibroscan) is a promising technique to detect fibrosis in an non-invasive manner.

No studies are yet published on transient elastography in a large cohort of children with CF.

Study objective

Primary objectivel: assessment of liver fibrose in children with cystic fibrosis, using transient elastography (Fibroscan). Results will be compared with other surrogate markers of CFRLD: liver ultrasonography and biochemical markers: AST, ALT, PT, platelet count, gamma-GT, alkaline phosphatase, bilirubin, albumin),

Secundary objective: to determine the incidence of CFRLD in a large cohort of patients, 2. to evealuate risk factors to develop CFRLD: like FEV1, CFTR-mutation, nutritional status and pancreatic insufficiency.

Study design

Crossectional, monocentre cohort studie, in which all children eligible for inclusion will be included at the moment they visit the CF center for their yearly check-up.

Study burden and risks

Patient will lie down for 30 minutes on the examination table (on the back or on the side).

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

Children with cystic fibrosis treated in the Erasmus Medical Centre Rotterdam / Sophia Children's Hospital, age 2 - 18 years, written informed consent.

Exclusion criteria

Age 0 - 2 year, measurement with Fibroscan is not feasible, as a result of small intercostal margins and/or ascits

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2008

Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	27-11-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL18187.078.07