Long-term neurodevelopment in patients treated for biliary atresia

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This study aims to investigate neurodevelopment in primary school children surviving biliary atresia when compared to a healthy reference group. Second aim is to identify prognostic factors associated with a worse outcome in these children.

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

Summary

ID

NL-OMON33497

Source
ToetsingOnline

Brief title
NDBA

Condition

- Hepatic and hepatobiliary disorders
- Developmental disorders NEC

Synonym
bile duct atresia, biliary atresia

Research involving
Human

Sponsors and support

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

Intervention

Keyword: biliary atresia, children, neurodevelopment

Outcome measures

Primary outcome

Neurodevelopment. More specific: intelligence, memory, attention, planning

skills, inhibition control, motor skills and visuomotory integration

Secondary outcome

Riskfactors for neurodevelopment impairment

Study description

Background summary

Biliary atresia is a peri-natal liver disease of unknown etiology in which the extrahepatic bile ducts obliterate. The only option for cure is resection of the fibrotic tissue and re-establishing bile-flow via a porto-enterostomy, in which a bowel loop is anastomosed to the liver. Despite a successful operation, liver fibrosis often progresses. Complications such as cholangitis or esophageal varices due to progressive fibrosis/cirrhosis occur frequently, and one third of the patients will need a liver transplantation before the second year of life. Only some 20% of patients reach their twenties with their own liver.
As early childhood is a time of critical brain growth severe (liver) disease has the potential to interfere with the developing brain. As our population consists of children with isolated biliary atresia which do not have other defects, this group provides an excellent opportunity to assess the effects of liver disease and possible transplantation in early childhood on neurodevelopment, such as the development of memory, attention, planning skills, inhibition control and visuomotory integration. Besides lengthy and multiple hospitalizations, other factors associated with severe liver disease such as malnutrition and encephalopathy may disrupt development.
Little is known about neurodevelopment in children surviving biliary atresia. Early identification of subgroups at risk for neurodevelopment impairment may offer the possibility to intervene in an earlier stage, thereby improving outcome with regards to school functioning and every day life.

Study objective

This study aims to investigate neurodevelopment in primary school children surviving biliary atresia when compared to a healthy reference group. Second aim is to identify prognostic factors associated with a worse outcome in these children.

Study design

Observational cohort study.

Study burden and risks

Patient and his/her family are confronted with a diagnosis they might have repressed all these years. Another possible burden could be that the patient becomes tired (physically and/or mentally) by the end of the testing session, since the examination will take 2 * 2.5 hours. However, previous studies in our department have shown that this is a rare event.

Children experiencing significant impairment in various areas of their cognitive and motor function are at risk of lagging behind in school and developing psychosocial problems in adolescence and early adulthood. The identification of possible risk factors in patients with biliary atresia associated with a worse neurodevelopmental outcome might enable us to identify these patients at an earlier stage, which might offer therapeutical benefits as early intervention/counseling has proven to be beneficial to the outcome.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children surviving biliary atresia with or without native liver who are currently between 6 and 12 years of age

Exclusion criteria

- Age > 6 or <12 years
- Syndromal biliairy atresia (with associated anomalies)
- Developmental/genetic disorders (such as autism, Down's syndrome)
- Language barrier

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-07-2019

Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL28279.042.09