Neurodevelopmental outcome and quality of life in infants with (congenital) liver disease

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27464

Source
Nationaal Trial Register

Brief title
COLINO

Health condition

Neurodevelopmental outcome
Congenital liver disease
Biliary Atresie
Liver transplantation
Behavioural problems
Quality of life

Neurologische uitkomst
Ontwikkelingsproblemen
Kwaliteit van leven
Aangeboren leveraandoeningen
Galgangatresie

Sponsors and support

Primary sponsor: -
Source(s) of monetary or material Support: MLDS

Intervention

Outcome measures

Primary outcome

Neurodevelopmenatal outcome

Quality of Life

Secondary outcome

Risk factors for impaired neurodevelopmental outcome / Quality of life

Study description

Background summary

Background

Congenital liver disorders often present shortly after birth, and in a large number of infants this leads to a liver transplantation before the age of 18 years. Previous studies showed that children who underwent a liver transplantation often have neuropsychological developmental problems. Recently we performed a pilot study in which the neuropsychological development at school age (6-12 years) in children with biliary atresia was examined. This analysis showed that these children achieve poorer results in motor, cognitive and behavioral tests compared to their healthy peers. The reason for these developmental problems is still unclear.

Methods

All children born in the Netherlands and Denmark with congenital

liver disease will be asked to undergo validated neuropsychological tests, at different ages (3 months post-term, 18 months and between 6 and 12 years old). The results of these tests

are correlated with different clinical parameters and risk factors to identify those children at high-risk for developmental problems.

Expected results

We expect to give an overview of the neuropsychological development of children born with congenital liver disease at school age. And furthermore to identify risk factors, in this population, for impaired neuropsychological development. Early identification of those infants at high risk for developmental problems may give us the ability to provide extra guidance or treatment in order to promote their quality of life and social participation.

Study objective

Infants with congenital liver disease and/or who underwent a liver transplantation < 5 year will have more neurodevelopmental problems and an impaired quality of life at school age when compared to healthy peers.

Study design

School age (6-12 years of age)

Intervention

-

Contacts

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Eligibility criteria

Inclusion criteria

- All infants with congenital liver disease in the Netherlands.

- All infants who had a liver transplantation < 5 year in the Netherlands.

Exclusion criteria

- Deceased infants.

-Neurodevelopmental sequelae due to other problems (e.g. syndromal)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2016
Enrollment:	75

Type:	Anticipated

Ethics review

Positive opinion

Date:	25-10-2016
Application type:	First submission

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
NTR-new	NL6060
NTR-old	NTR6207
Other	UMCG Research Register : 201600843

Study results