Research to the possible assciation between Chlamydia infection and the development of biliary atresia.

No registrations found.

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

Summary

ID

NL-OMON28565

Source
NTR

Brief title
BACHERA

Health condition

Extrahepatic Biliary Atresia, Chlamydia infection

Sponsors and support

Primary sponsor: Paul Fockens, MD, PhD
Department of Gastroenterology and Hepatology
Academic Medical Center
The Netherlands
Source(s) of monetary or material Support: Paul Fockens, MD, PhD
Department of Gastroenterology and Hepatology
Academic Medical Center
The Netherlands

Intervention

Outcome measures

Primary outcome

The presence of Chlamydia IgA antibody in serum of Dutch patients with biliary atresia, compared to the control group. The presence of Chlamydia in liver tissue (liver biopsy and fibrotic remnant obtained during Kasai operation) of BA patients as compared to controls, examined by PCR as well as Chlamydia-specific staining by immunohistochemistry.

Secondary outcome

The presence of Chlamydia IgA antibody in serum of mothers of patients with biliary atresia, compared to the presence of Chlamydia IgA antibody in serum of mothers of the control group and the presence of Chlamydia IgA antibody in the general population.

Study description

Background summary

Rationale: The aetiology of perinatal biliary atresia is unknown, but the cause is probably multifactorial. Even though many viruses have been described as possible causative agents for biliary atresia, there are little data about the association between bacterial microorganism and biliary atresia.
Chlamydia infection could lead to the chronic inflammation and obliteration of bile ducts by the induction of an antibody response against heat shock protein 60. In a cohort of English patients we found a significant higher prevalence of Chlamydia antibodies in serum of children with biliary atresia compared to controls.

Objective: To confirm that previous or persisting infection with Chlamydia is associated with the development of perinatal biliary atresia.
Furthermore to investigate whether the Chlamydia infection is contracted by vertical transmission from the mothers.

Study design: Multicentre centre case control study.

Study population: 19 patients younger than 12 years with biopsy proven biliary atresia, who are monitored at the outpatient clinic and their mothers, controlled by 15 patients younger than 12 years with hepatoblastoma, who are monitored at the outpatient clinic and their mothers.

Main study parameters/endpoints: The presence of Chlamydia IgA antibodies in serum, PCR and immunohistochemistry for Chlamydia in liver tissue of children diagnosed with biliary atresia, as well as the presence of Chlamydia IgA antibodies in the serum of their mothers.

Study objective

Previous or persisting infection with Chlamydia is associated with perinatal biliary atresia

Study design

Aim is to complete inclusion within two years after strat date

Intervention

Mothers will undergo one venapuncture. Biliary atrsia patients and controls will not be exposed to extra interventions.

Contacts

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Eligibility criteria

Inclusion criteria

• Biopsy proven biliary atresia

• Underwent Kasai operation

• Liver tissue stored at the Department of Pathology

• Outpatient follow up in the Academic Medical Center, Amsterdam or University Medical Centre Groningen

• Younger than 12 years

•Informed consent of custodial parent(s) or guardian, for inclusion of their child

• Informed consent of the mother for the withdrawal of maternal blood for ELISA on Chlamydia

Exclusion criteria

• Patients with embryonic biliary atresia

• Older then 12 years

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-11-2013
Enrollment:	34
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-05-2014
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	NL4136
NTR-old	NTR4640
Other	NL45157.018.13 : protocol ID

Study results