The Association between Chlamydia infection and Extrahepatic Biliary Atresia, a case control study

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON38798

Source
ToetsingOnline

Brief title
BACHERA

Condition

- Hepatobiliary disorders congenital

Synonym
bile duct atresia, vanishing bile ducts

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Chlamydia, Extrahepatic biliary atresia

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.

In case indications for DNA abnormalities will arise, the remainder of the serum will be used for DNA analysis.

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

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.

Study 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 burden and risks

There will be no risk or burden for the children, who will undergo venapuncture for follow-up purposes and will not have to undergo extra venapuncture for this research. As biliary atresia is a disease of the young children, this study can only be performed in this patient group. The mothers will have to undergo one venapuncture, during which one tube of blood will be taken. Possible risk is the occurrence of a haematoma as complication of the venapuncture, which is regarded as a minor transient burden. No extra visits to the hospital are necessary.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

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 then 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 invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-11-2013
Enrollment:	68
Type:	Actual

Ethics review

Approved WMO

Date:	16-10-2013
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	NL45157.018.13