Intraoperative bile duct visualisation in children with biliary atresia using a fluorescence camera system: a pilot study

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The primary objective is to confirm the diagnosis of biliary atresia by visualisation of the (remaining) biliary tract using fluorescence cholangiography.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bile duct disorders
Study type	Observational invasive

Summary

ID

NL-OMON32475

Source
ToetsingOnline

Brief title
Fluba

Condition

- Bile duct disorders
- Gastrointestinal therapeutic procedures

Synonym
Biliary atresia, infantile bile duct fibrosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Project galweg imaging. De Cock Stichting.

Intervention

Keyword: Bile duct imaging, Biliary atresia, Fluorescence

Outcome measures

Primary outcome

The main endpoint is confirmation of the diagnosis biliary atresia, defined as

fluorescent signal in the liver and possibly proximal remaining biliary

structures without continuation into the duodenum.

Secondary outcome

None.

Study description

Background summary

Biliary atresia (BA) is a cholangiopathy starting or progressing soon after birth that renders the extrahepatic bile ducts obliterated. The disease is fatal if untreated, and even with treatment the majority of children will need liver transplantation within several years. The mainstay of treatment for BA is portoenterostomy: the Kasai procedure. The Kasai procedure consists of resection of the fibrotic hilar plate followed by anastomosis of a loop of bowel onto the liver: the porto-enterostomy.The outcome (need for liver transplantation and survival) is largely dependent on the success of the surgical procedure, i.e. achieving restoration of bile flow.
Currently the intraoperative cholangiogram is the method of choice to confirm the presence of BA and to provide the surgeon with information on the anatomy of the remaining biliary structures. This cholangiogram is the first step in the operation, and when the diagnosis of biliary atresia is confirmed a Kasai procedure is performed.
The intraoperative cholangiogram has limitations: it can be accompanied by leakage of contrast, and thus lead to erroneous conclusions, it is a time and personnel-consuming procedure and it exposes the young infant (1-3 months) to hazardous radiation. The injection procedure can be technically challenging because of the small size of biliary structures.
In recent years fluorescence camera systems have emerged that allow in vivo

imaging of bile ducts using an exogenous fluorophore in combination with a fluorescence camera system. Fluorescence imaging with intravenously administered ICG could form an easily applicable and safe alternative to cholangiography with radiocontrast.

Study objective

The primary objective is to confirm the diagnosis of biliary atresia by visualisation of the (remaining) biliary tract using fluorescence cholangiography.

Study design

A phase 0 interventional non-randomized pilot study

Study burden and risks

The burden of the study for participants consists of
- an intravenous injection with ICG
- possibly an injection with ICG into the gallbladder
- prolonged surgery time up to 30 minutes
The main risk associated with intravenous injection of ICG is anaphylactic reaction, which occurs in less than 1/10000 cases, at higher doses than we will use in this study. Escape medication will be available in the operating room to intervene if necessary. The extra risk of infection is negligible: the camera will be covered with specially designed sterile drapes which have been tested and approved by the UMCG technical service.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children < 60 days with suspected biliary atresia

Exclusion criteria

History of iodine allergy or anaphylactic reactions to insect bites or medication. Presence or history of hyperthyroidism. Severe renal or liver failure.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2009
Enrollment:	4
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	ICG pulsion
Generic name:	indocyanine green: 2-{7-[1.1-dimethyl-3-(4-sulfobutyl)-benz[e]indolin-2-ylidene]-1,3,5-heptatrienyl}
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	15-01-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	26-01-2010
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Not approved Date:	08-11-2010
Application type:	Amendment
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
EudraCT	EUCTR2009-014886-21-NL
CCMO	NL29334.042.09