

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

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON25613

### Source

Nationaal Trial Register

### Brief title

FLUBA

### Health condition

Biliary atresia

## Sponsors and support

**Primary sponsor:** University Medical Centre Groningen

**Source(s) of monetary or material Support:** University Medical Centre Groningen

## Intervention

## Outcome measures

### Primary outcome

Visualisation of the (remnant) biliary structures.

## Secondary outcome

N/A

## Study description

### Background summary

Conventional cholangiography in children with biliary atresia is a cumbersome procedure that is not always successful. Fluorescence cholangiography may provide a simpler, safer method of visualising the (remnant) extrahepatic bile ducts.

### Study objective

The diagnosis of biliary atresia may be confirmed by intraoperative fluorescence cholangiography using intravenously or biliary administered indocyanine green.

### Study design

Intraoperative imaging.

### Intervention

1. Intravenous injection with ICG;
2. Intrabiliary injection with ICG;
3. Imaging using a near-infrared fluorescence camera.

All children receive intravenous injection with ICG. If no signal is received peroperative, intrabiliary injection is administered.

## Contacts

### Public

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## Eligibility criteria

### Inclusion criteria

Children in whom billiary atresia is suspected scheduled to undergo Kasai portoenterostomy.

### Exclusion criteria

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

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	21-01-2010

Enrollment: 4  
Type: Anticipated

## Ethics review

Positive opinion  
Date: 19-01-2010  
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	NL2053
NTR-old	NTR2170
Other	UMC Groningen : BA_BICG_UMCG_1
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A