

# Fluorescentiebeeldvorming van de galwegen tijdens kijkoperaties van de galblaas.

No registrations found.

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

## Summary

### ID

NL-OMON27461

### Source

NTR

### Brief title

NIRFC-LC

### Health condition

laparoscopic cholecystectomy, extra-hepatic bile ducts

## Sponsors and support

**Primary sponsor:** Maastricht University Medical Centre (MUMC+)

**Source(s) of monetary or material Support:** Maastricht University Medical Centre (MUMC+)

## Intervention

## Outcome measures

### Primary outcome

12-09-2012: Change:

Fluorescence identification of the extra-hepatic bile ducts and confirmation of the arterial

anatomy, comparing the conventional white light image to the ICG image.

### **Secondary outcome**

1. Fluorescence of bile ducts on different time points after injection;
2. Opinion of the surgeon regarding the application of fluorescence imaging during laparoscopic cholecystectomy.

## **Study description**

### **Background summary**

Laparoscopic cholecystectomy is one of the most commonly performed endoscopic procedures in gastrointestinal surgery. Bile duct injury (BDI) during this surgery is rare but constitutes a serious complication (0.3-0.7%). Misidentification of biliary anatomy during laparoscopic cholecystectomy appears to be the largest cause of BDI. Intraoperative cholangiography (IOC) is advised to reduce the risk of BDI. However, this imaging technique is only used selectively. The process takes time, radiation exposure is involved and additional equipment and manpower for the proceedings are required. Moreover, worldwide consensus about the implementation of IOC is lacking.

Fluorescence cholangiography with preoperative indocyanin green (ICG) administration is a promising new technique for easier intraoperative visualization of the biliary anatomy and thereby it could improve the outcome – safety and efficiency – of laparoscopic cholecystectomy.

Standard laparoscopic cholecystectomy will be performed, after preoperative intravenous administration of the near-infrared fluorescence dye indocyanine green. Using a modified laparoscopic device (for both conventional and fluorescence imaging) the extra-hepatic bile ducts will be visualized non-invasively.

12-09-2012: Additional intervention/observation in the last 20 patients: Simultaneous fluorescence imaging of the arterial anatomy at establishment of critical view of safety; after repeat ICG administration.

### **Study objective**

Improved and earlier identification of extra-hepatic bile ducts by intraoperative fluorescence imaging.

### **Study design**

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Primary and secondary outcomes will be assessed during (and after) surgical procedure.

## **Intervention**

Standard laparoscopic cholecystectomy will be performed, after preoperative intravenous administration of the near-infrared fluorescence dye indocyanine green. Using a modified laparoscopic device (for both white light, and ICG imaging) the extra-hepatic bile ducts will be visualized non-invasively.

12-09-2012: Addition:

Repeat intravenous ICG injection at establishment of critical view of safety for simultaneous fluorescence imaging of bile ducts and arterial anatomy.

## **Contacts**

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## **Eligibility criteria**

### **Inclusion criteria**

1. Patients scheduled for a laparoscopic cholecystectomy;
2. Males and females (not pregnant);
3. Age >18 years;
4. Normal liver and renal function;

5. No history of allergy for iodine or indocyanine green.

## Exclusion criteria

1. Liver or renal insufficiency;
2. History of allergy for iodine or indocyanine green;
3. Patient pregnant or lactating;
4. Aged < 18 years.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
<b>Control:</b>	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2011
Enrollment:	30
Type:	Actual

### IPD sharing statement

**Plan to share IPD:** Undecided

## Ethics review

Positive opinion	
Date:	22-12-2011
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	NL3063
NTR-old	NTR3211
Other	METC azm/UM / CCMO : 11-2-078 / NL38521.068.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A