Real-time Intraoperative Near-Infrared Fluorescence Cholangiography Assisted Laparoscopic Cholecystectomy: A pilot study

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The main goal of this pilot study is to test feasibility of the present commercially available near-infrared fluorescence cholangiography (NIRFC) laparoscopic device during the laparoscopic cholecystectomy.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal inflammatory conditions
Study type	Interventional

Summary

ID

NL-OMON37688

Source
ToetsingOnline

Brief title
NIRFC-LC

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
cholecystitis, gall stones, inflammation of the gall bladder

Research involving
Human

Sponsors and support

Primary sponsor: azM (academisch ziekenhuis Maastricht)
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Bile Duct Injury, Critical View of Safety, Laparoscopic Cholecystectomy (LC), Near-Infrared Fluorescence Cholangiography (NIRFC)

Outcome measures

Primary outcome

- Identification of biliary anatomy

- Identification of critical view of safety

Assessment of NIRFC technique:

- Video analysis

- Intraoperative registration/evaluation form

- Recognition of the biliary anatomy (at set time points: every 5-10 minutes)

and moment of obtaining CVS

- Speed and efficiency of the procedure

- Safety of the procedure

Time measurement:

- time until CVS is obtained

- time until fluorescence/conventional imaging is obtained of individual

biliary structures

- total operating time

Later on, this can be compared to conventional laparoscopic cholecystectomy

procedures.

Secondary outcome

We will register complications caused during the procedure:

- Bile duct injury

- Vascular injury

We will register unsuspected adverse effects of the administered fluorescent

dye

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.

Possible benefits of intraoperative fluorescence cholangiography compared to conventional intraoperative cholangiography are the following:
1. The technique can save time.
2. Bile duct injury possibly caused by insertion of a trans-cystic catheter can be avoided.
3. It is easier to apply, since only one preoperative injection of ICG is needed. This allows the surgeon to obtain fluorescence images at any time,

without the aid of radiology staff.
4. The bile ducts may be better identifiable from the surrounding tissues.
5. It is a safe technique without radiation exposure; administration of ICG also has a very small risk of an allergic reaction (0.003%) and has already been approved for clinical use.

Study objective

The main goal of this pilot study is to test feasibility of the present commercially available near-infrared fluorescence cholangiography (NIRFC) laparoscopic device during the laparoscopic cholecystectomy.

Study design

A prospective observational pilot study:
- The study will be conducted in the Maastricht University Medical Centre+ (MUMC+).
- The operations will be performed by two gastrointestinal surgeons, with extensive experience in laparoscopic surgery.
- As usual, Critical View of Safety (CVS) technique will be used during the operation.
- Visual recordings will be made during dissection to obtain CVS.

Storz® will provide the necessary apparatus (NIR fluorescence laparoscope, modified light source and light cable) and technological support.

ICG will be delivered by the logistics department of the hospital pharmacy of MUMC+.

After surgery the NIRFC technique will be assessed by an intraoperative registration/evaluation form.
Visual recordings will be analyzed.

TNO, Department of Imaging, will also provide technological support for image processing.

Intervention

Study subjects receive 2 intravenous injections of 1ml ICG (2.5mg/ml).

Comment:
- 1 x 1ml ICG injection preoperative (directly after induction of anesthesia), in order to visualize the extra-hepatic bile ducts during the laparoscopic procedure using the fluorescence technique.
- 1 x 1ml ICG injection intraoperative (at the moment of determination of CVS / critical view of safety), in order to visualize the arterial phase using the

fluorescence technique (<10 seconds after this injection).

Study burden and risks

Compared with standard care, patients have to receive one preoperative and one intraoperative intravenous injection of a contrast agent, indocyanin green (ICG). This is the only additional invasive action for the patient.
Initially, patients participating in this study will not benefit from the application of NIRFC during the surgical procedure.
The administration of ICG (FDA approved and already used for several clinical diagnostic indications) and the modified laparoscope itself are not related with any kind of additional risk for the patient.

Only a small sample size is needed, as it is expected that the outcome of this study will be of great importance for the further application of the NIRFC technique in laparoscopic cholecystectomy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients scheduled for a laparoscopic cholecystectomy
Able to understand the nature of the study and what will be required of them
Males and females (not pregnant)
Age >18 years
Normal liver and renal function
No hypersensitivity for iodine
Willing to participate

Exclusion criteria

Not able to give written informed consent
Liver or renal insufficiency
Iodine hypersensitivity
Pregnant women
Aged < 18 years
Not willing to participate

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Fluorescence laparoscopy device (incl. laparoscope;light source;light cable)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-11-2011
Application type:	First submission
Review commission:	MEC academisch ziekenhuis Maastricht/Universiteit Maastricht, MEC azM/UM (Maastricht)
Approved WMO Date:	28-03-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL38521.068.11