Optimalization of real-time intraoperative near-infrared (NIR) fluorescence cholangiography during laparoscopic cholecystectomy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23566

Source
NTR

Brief title
GREEN LIGHT

Health condition

intraoperative clarification of bile duct anatomy using NIR fluorescence imaging

Sponsors and support

Primary sponsor: Leiden University Medical Center (LUMC)
Source(s) of monetary or material Support: Leiden University Medical Center (LUMC)

Intervention

Outcome measures

Primary outcome

- Identification of bile ducts using laparoscopic NIR fluorescence imaging during laparoscopic

cholecystectomy.

Secondary outcome

-Distinctive character of fluorescence imaging of bile ducts vs. liver after injection of either 5 or 10 mg ICG after several time points

-Evaluation of applicability of NIR fluorescence imaging during laparoscopic cholecystectomy by performing questionnaire after surgery

Study description

Background summary

Bile duct identification during laparoscopic cholecystectomy can be challanging. Near-infrared fluroescence cholangiography is an innovative technique enabling real-time identification of bile duct anatomy after injection of the fluorophore indocyanine green (ICG).

However, distinction between liver and bile ducts
is of utmost important to make this technique widely applicable and usefull. No optimal dose of ICG and time of administration have ever been investigated. In the current study, we aim to optimize both factors.

Study objective

Delayed fluorescence imaging is optimal for visualization of bile ducts compared to the surrounding liver.

Study design

The primary and secondary timepoints will be assessed during and after surgery

Intervention

Patients will be divided in several groups and receive either 5 or 10 mg ICG, administered (iv)30 min, 2h, 4h, 6h or 24 hours prior to surgery. Standard laparoscopic cholecystectomy will be performed. Fluorescence imaging will be frequently performed during surgery using the Karl Storz HD fluorescence laparoscope.

Contacts

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Eligibility criteria

Inclusion criteria

Patients (>18 years old) suffering from benign gallbladder pathology, planned to undergo laparoscopic cholecystectomy

Exclusion criteria

1. Allergy for jodide or indocyanine green;

2. Hyperthyroidism or autonomous thyroidal adenoma;

3. Pregnancy;

4. Severe renal impairment (eGFR<55)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-11-2014
Enrollment:	28
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-01-2016
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	NL5488
NTR-old	NTR5623
Other	Addendum U : P10.001

Study results

Summary results
N/A