Real-time intraoperatieve nabij-infrarode fluorescentie cholangiografie tijdens laparoscopische cholecystectomie.

No registrations found.

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

Summary

ID

NL-OMON25103

Source
Nationaal Trial Register

Brief title
GREEN LIGHT

Health condition

cholecystolithiasis

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

Primary outcome parameter is the number of identified bile ducts.

Secondary outcome

Secundary parameters are the signal-to-background ratios measured in patients that recieved ICG, and the number of identified structures of the biliray tree.

Study description

Background summary

During laparoscopic cholecystectomy, common bile duct injury is a rare but severe complication. Optical imaging using near-infrared (NIR) fluorescence has recently been introduced to reduce the risk of injury by real time visual guidance. The aim of the current study is to optimize dose and timing of ICG for near-infrared cholangiography using laparoscopic fluorescence imaging system.

Study objective

Fluorescent near-infrared imaging can accurately detect bilary antomy during laparoscopic cholecystectomy.

Study design

The primary and secondary outcomes will be assessed during surgery.

Intervention

Standard laparoscopic cholecystecomy will be performed. During surgery, the near-infrared dye ICG will be injected and the bile ducts will be visualized non-invasively using a laparoscopic camera system.

Contacts

Public
Leiden University Medical Center (LUMC),
Department of Surgical Oncology,
P.O. Box 9600
C.J.H. Velde, van de
Leiden 2300 RC
The Netherlands
+31 (0)71 5262309
Scientific
Leiden University Medical Center (LUMC),
Department of Surgical Oncology,

P.O. Box 9600
C.J.H. Velde, van de
Leiden 2300 RC
The Netherlands
+31 (0)71 5262309

Eligibility criteria

Inclusion criteria

1. Patients scheduled to undergo laparoscopic cholecystectomy;METC LUMC
2. Age above 18.

Exclusion criteria

1. History of allergy to iodine, shellfish, indocyanine green, human serum albumin and/or history of hyperthyroidism or severe renal impairment;METC LUMC
2. Patient pregnant or lactating.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2012
Enrollment:	15
Type:	Anticipated

Ethics review

Positive opinion

Date:	05-11-2012
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	NL3530
NTR-old	NTR3686
Other	METC LUMC : P10.001
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A