Near-infrared Fluorescence Cholangiography assisted Laparoscopic Cholecystectomy versus Conventional Laparoscopic Cholecystectomy (FALCON): a multicenter randomized controlled trial

Published: 04-11-2015
Last updated: 20-04-2024

The main objective of this study is to evaluate whether earlier establishment of Critical View of Safety can be obtained during laparoscopic cholecystectomy, by applying NIRF laparoscopic imaging as an adjunct to conventional laparoscopic imaging...

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

Summary

ID

NL-OMON47297

Source
ToetsingOnline

Brief title
FALCON

Condition

- Gastrointestinal inflammatory conditions
- Gastrointestinal therapeutic procedures

Synonym
cholecystolithiasis, gall stones disease

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Karl Storz

Intervention

Keyword: Critical View of Safety (CVS), Indocyanine Green (ICG), Laparoscopic Cholecystectomy (LC), Near-Infrared Fluorescence Imaging (NIRF)

Outcome measures

Primary outcome

Primary endpoint of this trial is:

- "time to identification of CVS"

This endpoint is used as a surrogate for bile duct identification without

surgical exploration.

Secondary outcome

Secondary endpoints are:

- time until identification of the transition of the cystic duct in the

gallbladder during dissection of CVS;

- visualization of CVS and visualization of the transition of the cystic duct

and cystic artery in the gallbladder;

- total surgical time;

- intraoperative bile leakage from the gallbladder or cystic duct;

- bile duct injury;

- postoperative length of hospital stay;

- complications due to the injected contrast agent;

- conversion to open cholecystectomy.

- postoperative complications (until 90 days after the surgical procedure)

- cost-minimisation.

Study description

Background summary

Laparoscopic cholecystectomy (LC) is one of the most commonly performed laparoscopic procedures in gastrointestinal surgery. Bile duct injury during this procedure is rare but constitutes a serious complication (0.3-0.7%). Misidentification of the extra-hepatic bile duct anatomy during laparoscopic cholecystectomy is the main cause of bile duct injury.

The Critical View of Safety (CVS) technique was introduced to reduce the risk of bile duct injury. To establish CVS, two windows need to be created: one window between the cystic artery, cystic duct and gallbladder, another window between the cystic artery, gallbladder and liver. The CVS technique is especially aimed at mobilizing the gallbladder neck from the liver, in order to obtain a circumferential identification of the cystic duct.

Intraoperative cholangiography has been advised to reduce the risk of bile duct injury. However, this radiological imaging of the biliary tree is only used selectively, as the process takes time, radiation exposure is involved and additional equipment and manpower for the procedure are required. Therefore, worldwide consensus about implementation of intraoperative cholangiography is still lacking.

Near-infrared fluorescence (NIRF) imaging after intravenous injection of indocyanine green (ICG) is a promising new technique for easier intraoperative recognition of the biliary anatomy. It may help improve the outcome of laparoscopic cholecystectomy. ICG is cleared quickly and exclusively by the liver after intravenous administration. Neither radiological support nor additional intervention, such as opening the biliary tree, is required. The NIRF laparoscopy technique using ICG has been evaluated in various animal models and in open, laparoscopic, and single-incision laparoscopic cholecystectomy. Promising results were presented for successful intraoperative identification of the common bile duct and the cystic duct, compared to conventional laparoscopic imaging. Another clinical study showed that the NIRFC technique provides significantly earlier identification of the extra-hepatic bile ducts during the CVS dissection phase: up to 10 minutes earlier identification of cystic duct and common bile duct could be obtained. Real-time simultaneous imaging of the hepatic and cystic arteries can also be obtained.

Despite the encouraging results from these (pre)clinical feasibility studies, wide clinical acceptance for the routine use of ICG fluorescence laparoscopy is still lacking due to the absence of reliable clinical data. Therefore, a multicenter randomized clinical study is desirable to assess the potential added value of the fluorescence imaging technique during laparoscopic cholecystectomy in order to perform an even more safe procedure leading to a reduction in the vascular and bile duct injuries. This study will compare NIRF assisted laparoscopic cholecystectomy to conventional laparoscopic cholecystectomy.

Study objective

The main objective of this study is to evaluate whether earlier establishment of Critical View of Safety can be obtained during laparoscopic cholecystectomy, by applying NIRF laparoscopic imaging as an adjunct to conventional laparoscopic imaging versus conventional laparoscopic imaging alone.

Study design

A multicenter randomized controlled trial, with two randomization arms:
- NIRF-LC group: this group of patients will undergo near-infrared fluorescence cholangiography assisted laparoscopic cholecystectomy;
- CLC group: this group will undergo conventional laparoscopic cholecystectomy.

Planned duration of the project: 2 year

This study is being performed by the Departments of Surgery of three University Medical Centers and two large peripheral training hospitals in the Netherlands, one University Hospital in Italy, a clinic in Germany and two potential centers in Belgium and the United Kingdom.

- Maastricht Universitair Medisch Centrum + (MUMC +, Maastricht, the Netherlands)
- Leids Universitair Medisch Centrum (LUMC, Leiden, the Netherlands)
- Catharina-ziekenhuis Eindhoven, the Netherlands;
- IRCCS - Ca' Granda, Policlinico hospital, Milan, Italy;
- Clinic for general, visceral and vascular surgery, Asklepios Westklinikum Hamburg, Germany
- Colchester University Hospital, Colchester, United Kingdom

Intervention

The NIRF-LC group will undergo near-infrared fluorescence cholangiography (in combination with one preoperative and one per-operative intravenous injection of contrast agent ICG) assisted laparoscopic cholecystectomy.

The CLC group will undergo conventional laparoscopic cholecystectomy (CLC).

Study burden and risks

Compared with standard care, patients in the NIRF-LC group have to receive one preoperative and one per-operative intravenous injection of ICG. This is the only additional (minimally) 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, previously used in the NIRFC-LC pilot study: NL38521.068.11) and the laparoscopic fluorescence imaging system are not related with any kind of additional risk for the patient.

Despite the encouraging results from several (pre)clinical feasibility studies, wide clinical acceptance for the routine use of ICG fluorescence laparoscopy is still lacking due to the absence of reliable and validated clinical data. A randomized clinical study is desirable to assess the potential added value of the NIRF imaging technique during laparoscopic cholecystectomy. The FALCON trial will provide evidence on the benefit of standard application of NIRF imaging during laparoscopic cholecystectomy. Strong evidence in favor of routine implementation of this new imaging technique during laparoscopic cholecystectomy, the most commonly performed laparoscopic procedure worldwide, will probably lead to worldwide routine application of the NIRF technique. Therewith long term sustainability of this research project is guaranteed.

Contacts

Public
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL
Scientific
Medisch Universitair Ziekenhuis Maastricht

P. Debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Male and female patients, aged 18 years and above
Scheduled for elective laparoscopic cholecystectomy
Normal liver and renal function
No hypersensitivity for iodine or ICG
Able to understand nature of the study procedures
Willing to participate and with written informed consent
Physical Status Classification: ASA I / ASA II

Exclusion criteria

Age < 18 years
Liver or renal insufficiency
Known iodine or ICG hypersensitivity
Pregnancy or breastfeeding
Not able to understand nature of the study procedure
Physical Status Classification: ASA III and above

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-02-2016
Enrollment:	205
Type:	Actual

Medical products/devices used

Generic name:	Laparoscopic Fluorescence Imaging System (incl. laparoscope;light source;light cable)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-11-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	18-04-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	24-05-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-05-2018

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	NL47718.068.14
Other	volgt