Onderzoek naar het met een fluorescerende stof zichtbaar maken van de galwegen tijdens operatie voor het verwijderen van de galblaas in patiënten met gecompliceerd galsteenlijden

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24068

Source NTR

Health condition

Laparoscopy, Cholecystectomy, Bile ducts, Bile duct injury, Infrared, Complicated gallbladder disease

Sponsors and support

Primary sponsor: VU University Medical Center, Amsterdam **Source(s) of monetary or material Support:** Olympus (Tokyo, Japan)

Intervention

Outcome measures

Primary outcome

- 1. Time of identification of the common bile duct and the cystic duct
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- 2. Frequency of identification of the common bile duct and cystic duct
- 3. Feasibility of ICG in complicated gallbladder disease

Secondary outcome

- 1. Detection of biliary and arterial anatomic variations
- 2. Prevention and detection of bile duct injuries

Study description

Background summary

Injuries to the CBD are rare but serious complications with need for re-intervention, risk of permanent disability and prolonged hospital stay. Patients at risk for bile duct injury are those suffering from acute cholecystitis, biliary pancreatitis, bleeding, scarred or shrunken gallbladder due to previous infection, gallstones in Hartmann's pouch, a short cystic duct, Mirizzi's syndrome and abnormal biliary anatomy. With fluorescent imaging of the bile ducts during surgery, using Indocyanine green and a near-infrared camera, good results are reported in patients undergoing laparoscopic cholecystectomy with symptomatic gall stones. In patients at higher risk for per-operative bile duct injury, as defined by the inclusion criteria of this clinical trial, intra-operative cholangiogram is performed in order to visualize the bile ducts during surgery.

Methods:

Patients eligible for laparoscopic cholecystectomy in the setting of complicated gallbladder disease are included in the study. An intravenous injection of ICG is administered before induction of general anesthesia. During standard laparoscopic cholecystectomy, the near-infrared camera is used to visualize the biliary structures. At set times during surgery, identification of the bile ducts with the near-infrared and the conventional camera is done and scored by the investigator. Post-operative care is conform standard surgical procedures.

Study objective

Peroperative fluorescent imaging of the bile ducts will improve visibility and results in early identification of the common bile duct and the cystic duct during laparoscopic cholecystectomy in patients at risk for bile duct injury.

Study design

Per-operative: ICG-NIR vs conventional identification of bile ducts:

1. Before start of dissection

2. At Critical view of Safety

additionally: Early and late during dissection, before CVS is obtained

Intervention

Pre-operative patients receive 1 dosis of Indocyanine Green (ICG), which is a fluorescent contrast agent that is excreted by the liver into the bile. Per-operative a near-infrared laparoscopic camera is used to visualize the ICG in the bile ducts. During the laparoscopic cholecystectomy, both the conventional and near-infrared camera will be used to identify the common bile duct and cystic duct.

Contacts

Public

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Eligibility criteria

Inclusion criteria

acute cholecystitis, biliary pancreatitis, choledocholithiasis or cholecystolithiasis resulting in hospital admission, endoscopic retrograde pancreatic-cholangiography (ERCP) or percutaneous gallbladder drainage.

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Exclusion criteria

1. anti-convulsive medication, cyclopropane, bisulphite connexions, haloperidole, diamorphine, pethidine, morphine, nitrofurantoin, opium alkaloids, phenobarbital, phenylbutazon, probenicid, metamizole, rifamycine, methadone, sodium bisulphite

2. Allergy to ICG or lodine

3. Hypothyreoidism, Hyperthyreoidism.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

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INL	
Recruitment status:	Recruiting
Start date (anticipated):	01-12-2012
Enrollment:	30
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	10-07-2014
Application type:	First submission

Study registrations

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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	NL4537
NTR-old	NTR4680
Other	:

Study results

Summary results Not applicable