Fluorescentiebeeldvorming van de galwegen tijdens kijkoperaties van de galblaas.

Gepubliceerd: 22-12-2011 Laatst bijgewerkt: 18-08-2022

Improved and earlier identification of extra-hepatic bile ducts by intraoperative fluorescence imaging.

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27461

Bron
NTR

Verkorte titel
NIRFC-LC

Aandoening

laparoscopic cholecystectomy, extra-hepatic bile ducts

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre (MUMC+)
Overige ondersteuning: Maastricht University Medical Centre (MUMC+)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

12-09-2012: Change:

Fluorescence identification of the extra-hepatic bile ducts and confirmation of the arterial anatomy, comparing the conventional white light image to the ICG image.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Standard laparoscopic cholecystectomy will be performed, after preoperative intravenous administration of the near-infrared fluorescence dye indocyanine green. Using a modified laparoscopic device (for both conventional and fluorescence imaging) the extra-hepatic bile ducts will be visualized non-invasively.

12-09-2012: Additional intervention/observation in the last 20 patients: Simultaneous fluorescence imaging of the arterial anatomy at establishment of critical view of safety; after repeat ICG administration.

Doel van het onderzoek

Improved and earlier identification of extra-hepatic bile ducts by intraoperative fluorescence imaging.

Onderzoeksopzet

Primary and secondary outcomes will be assessed during (and after) surgical procedure.

Onderzoeksproduct en/of interventie

Standard laparoscopic cholecystectomy will be performed, after preoperative intravenous

administration of the near-infrared fluorescence dye indocyanine green. Using a modified laparoscopic device (for both white light, and ICG imaging) the extra-hepatic bile ducts will be visualized non-invasively.

12-09-2012: Addition:
Repeat intravenous ICG injection at establishment of critical view of safety for simultaneous fluorescence imaging of bile ducts and arterial anatomy.

Contactpersonen

Publiek

P. Debyelaan 25
R.M. Schols
Maastricht 6229 HX
The Netherlands
+31 (0)43 3881575

Wetenschappelijk

P. Debyelaan 25
R.M. Schols
Maastricht 6229 HX
The Netherlands
+31 (0)43 3881575

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients scheduled for a laparoscopic cholecystectomy;

2. Males and females (not pregnant);

3. Age >18 years;

4. Normal liver and renal function;

5. No history of allergy for iodine or indocyanine green.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Liver or renal insufficiency;

2. History of allergy for iodine or indocyanine green;

3. Patient pregnant or lactating;

4. Aged < 18 years.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-12-2011
Aantal proefpersonen:	30
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	22-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3063
NTR-old	NTR3211
Ander register	METC azm/UM / CCMO : 11-2-078 / NL38521.068.11;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A