Selective Indocyanine Green Injection of a Segmental Hepatic Artery Followed by Near-Infrared Fluorescence Guided Anatomical Liver Resection: A Feasibility Study

No registrations found.

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

Summary

ID

NL-OMON21492

Source
Nationaal Trial Register

Brief title
SELECT STUDY

Health condition

Hepatocellular carcinoma, intrahepatic cholangiocarcinoma, liver metastases

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: N.A.

Intervention

Outcome measures

Primary outcome

To investigate the feasibility of using intra-arterial ICG and embolization preoperatively to allow for liver segment visualization during anatomical liver resection.

Secondary outcome

1. Time ideal window between intervention radiology and operation will be increased after every two successful liver segment visualizations (contrast ratio of 1.6). The endpoint for this parameter is 24 hours, and will be confirmed in 4 consecutive patients.
2. Perioperative blood loss (Estimated Blood Loss (EBL) in mL by the operating team).
3. Operation time.(Time from ‘incision’ to ‘end of surgery’ in minutes as reported in the EPD)

Study description

Background summary

Rationale: Anatomical liver resections for hepatocellular carcinomas (HCCs) reduce tumor recurrence and may reduce blood loss and bile leakage.[1, 2] Intraoperative Indocyanine green (ICG) injected through the portal vein combined with fluorescent near infrared imaging has proven to improve precision of anatomical resection. However, intraoperative portal vein administration of ICG can be challenging, especially in laparoscopic procedures.[3] Recent feasibility studies showed promising results for intra-arterial selective ICG injection followed by embolization of the segmental artery using intervention radiology and hybrid operating rooms. Unfortunately, hybrid operating rooms are not available in all hospitals. Therefore, our intent is to perform the interventional radiological procedure separately, before the operation to facilitate access to the procedure, logistics, safe precious personnel and time. This approach is based on the results published in a case report recently.[4]

Objective: The primary objective is to investigate the feasibility of using intra-arterial ICG preoperatively to allow for liver segment visualization during anatomical liver resection.

Study design: Prospective, single center, open-label, non-randomized phase II trial. Total of 12 patients receiving the same treatment.

Study population: Patients aged over 18 years old and scheduled for open or laparoscopic anatomical liver resection due to primary liver malignancies, i.e. hepatocellular carcinoma and intrahepatic cholangiocarcinoma.

Intervention: Patients will receive preoperative angiography at least three hours before the operation, during which the artery of the segment(s) containing the tumor will be selectively catheterized with a microcatheter. Angiography and cone-beam CT are then performed to confirm that the correct segment has been catheterized. A mixture of ICG and lipiodol can then be injected to stain the segment. Lipiodol causes temporary vessel occlusion as recanalization of the artery usually occurs several days to weeks after the injection. After injection of this mixture, gel foam (Cutanplast®) will be injected to avoid wash-out of ICG.

Segmentectomy of the targeted liver segment(s) will then be performed using near infrared cameras for identification of the segment(s).

Main study parameters/endpoints: To investigate the feasibility of using intra-arterial ICG and embolization preoperatively to allow for liver segment visualization during anatomical liver resection.

Study objective

The primary objective is to investigate the feasibility of using intra-arterial ICG preoperatively to allow for liver segment visualization during anatomical liver resection.

Study design

Interim analysis after every two patients

Intervention

Patients will receive preoperative angiography at least three hours before the operation, during which the artery of the segment(s) containing the tumor will be selectively catheterized with a microcatheter. Angiography and cone-beam CT are then performed to confirm that the correct segment has been catheterized. A mixture of ICG and lipiodol can then be injected to stain the segment. Lipiodol causes temporary vessel occlusion as recanalization of the artery usually occurs several days to weeks after the injection. After injection of this mixture, gel foam (Cutanplast®) will be injected to avoid wash-out of ICG. Segmentectomy of the targeted liver segment(s) will then be performed using near infrared cameras for identification of the segment(s).

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Scheduled for open or laparoscopic anatomical liver resection;
2. Patients aged over 18 years old;
3. Has the ability to communicate well with the investigator in Dutch or English and willing to comply with the study design;
4. Signed informed consent prior to any study-mandated procedure.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
1. Previous major abdominal surgery
2. Known allergy or history of adverse reaction to ICG, lipiodol, gel foam, iodine or iodine contrast agents;
3. Severe liver insufficiency;
4. eGFR: <30;
5. Hyperthyroidism or a benign thyroid tumor;
6. Pregnant or breastfeeding women;
7. Scheduled for palliative surgery or terminally ill
8. Any condition that the investigator considers to be potentially jeopardizing the patients well-being or the study objectives (following a detailed medical history and physical examination);
9. Subject taking phenobarbital, phenylbutazone, primidone, phenytoin, haloperidol, nitrofurantoin, probenecid and/or metformin;
10. Emergency surgery.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2021
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	26-10-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 52161
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9004
CCMO	NL75171.058.21
OMON	NL-OMON52161

Study results