Perioperative Hepatic Blood Flow in relation to Hepatic Regeneration and Function following major Liver Surgery

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Ethical review	Approved WMO
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON48919

Source
ToetsingOnline

Brief title
RECOVERY Study

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Hepatobiliary therapeutic procedures

Synonym
Liver cancer, liver surgery

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Liver function, Liver surgery, Regeneration

Outcome measures

Primary outcome

Portal Venous Blood flow (Ultrasound)

Hepatic Artery Blood flow (Ultrasound)

Hepatic Artery Resistance Index (Ultrasound)

ICG retention after 15 minutes (ICG-R15)

ICG plasma disappearance rate (ICG-PDR)

Maximum Liver Function Capacity by (LiMAx)

Liver remnant volume by (CT Volumetry)

Secondary outcome

Routine laboratory Liver function parameters

Routine Hemodynamic parameters

Clinical Outcomes: length of stay, Ventilator time, ICU readmission, Death

Study description

Background summary

In high risk liver surgery patients, unhindered and swift liver regeneration is paramount to successful outcomes. Recent experimental and clinical studies have shown that alterations in hepatic blood flow is a driving force of liver regeneration. Patients with insufficient residual mass or disordered regeneration have an increased risk of severe postoperative complications including liver failure and death. However, there is currently no evidence or guidance how alterations in hepatic blood flow can help clinicians to preserve liver function and enhance liver regeneration after major liver surgery. Therefore, we want to observe the course of hepatic blood flow, liver function and liver regeneration after high risk liver surgery.

Furthermore, we aim to identify parameters or patterns associated with favourable outcomes such as sufficient liver regeneration and preservation of liver function after high risk liver surgery. The results of this study will facilitate identification of opportunities to design future intervention studies to improve outcomes for high-risk liver surgery patients.

Study objective

Aim of thus study is to observe and correlate the course of hepatic blood flow, liver function and liver regeneration after high risk liver surgery.
Furthermore we aim to identify ultrasound, liver function and routine hemodynamic parameters associated with increased liver regeneration after major liver surgery.

Study design

Prospective observational study with invasive measurements

Study burden and risks

Except the ICG and LiMAx liver function tests and CT-Volumetry scans, there are no risks associated with participation in this study.
It is known that ICG injection can very exceptionally (<1/10000) cause nausea, urticarial or an anaphylactoid or anaphylactic reaction. Therefore intravenous injection will only be performed by -or under direct supervision of- a physician and will be performed on a hospital ward or ICU.
The LiMAx test uses intravenous injection of 13C-methacetin, a prodrug of acetaminophen (paracetamol) which will be metabolized to acetaminophen by the liver. Since intravenous acetaminophen is also routinely used in patients after high-risk liver surgery, we do not expect an harmful effect of the intravenous administration of 13C-methacetin.
The CT volumetry scans will give additional radiation exposure. The radiation exposure has been calculated and presented to the Radiation Exposure Advisory Board, this evaluation is included in the dossier.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Major Hepatectomy defined as
- FLR <30% in normal liver
- FLR <40% in diseased liver including post-chemotherapy

Exclusion criteria

< 18 years
Intolerance or allergy to paracetamol or 13C-methacetin
Previous splenectomy
Child C cirrhosis
Concomitant RF/Microwave Ablation
Significant Cardiovascular disease
Pregnancy
No written and signed informed consent

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO

Date:	06-12-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL63662.078.18