Galileo trial

No registrations found.

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

Summary

ID

NL-OMON22479

Source
NTR

Brief title
GALILEO

Health condition

Liver surgery, Liver cancer, intraoperative fluid therapy

Sponsors and support

Primary sponsor: Academic Medical Center
Source(s) of monetary or material Support: Academic Medical Center

Intervention

Outcome measures

Primary outcome

- Total intraoperative blood loss

Secondary outcome

28-okt-2016 amendment:
- Kidney function day 1-5 (Na/K/Creat/Osm/Ureum, blood and (2x 12h a day) urine)

- RAAS system (aldosterone, renine, ADH in plasma), just before and after resection during the operation

- Outcome data: all complications

- Body weight and ankle & abdominal girth (pre-op and day 1,2,5)

- Microcirculatory measurements:

- Sublingual measurements pre-op, during the surgery (T0 baseline (after skin incision), T1 (at the end of the ischemia phase, during
the first VIO), T2 (30-60 minutes after reperfusion), 24, 48h and 5 days

- Abdominal organ measurements during the surgery T0 baseline (after skin incision), T1 (at the end of the ischemia phase, during the
first VIO), T2 (30-60 minutes after reperfusion).

- Photo of liver tissue (to identify measured area with the Cytocam).

- Liver tissue from the already resected part, for the use of the histology sample preparations

Study description

Background summary

NA

Study objective

The use of a GDFT protocol during liver surgery instead of the widely used LCVP regimen has no influence on blood loss.

Study design

pre-op until day 5

Intervention

- GDFT

- Low CVP

Contacts

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Eligibility criteria

Inclusion criteria

Adult patients, undergoing open liver resection and which are able to provide written informed consent

Exclusion criteria

• Age < 18

• Known pregnancy

• Known allergies to colloid fluids or contrast

• Pre-operative severe kidney dysfunction (GFR < 30).

• Severe decreased liver function disorders (i.e. PTT, APTT > 1.5 of normal) and/or low albumin)

• Significant ischemic heart disease, heart failure or severe arrhythmias

• Laparoscopic liver resection

• Minor resection (such as wedge resections)

• Liver resections in combination with biliary tract resections

• If no resection is performed

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2016
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	04-04-2016
Application type:	First submission

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
NTR-new	NL5677
NTR-old	NTR5821
Other	METC : 2016_004

Study results