Goal-directed versus restricted fluid management during major hepatic surgery; a double blind randomized controlled pilot trial

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON45945

Source
ToetsingOnline

Brief title
Galileo trial

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
Fluid therapy during liver surgery

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: anesthesiology, goal directed therapy, liver surgery, low cvp

Outcome measures

Primary outcome

Intraoperative blood loss

Secondary outcome

1) Surgical conditions (subjectively rated by the surgeon on a visual analogue scale from 0-10), duration of the liver resection phase, duration of Pringle maneuver), blood content in liver as measured by enhanced ultrasound (ESUS).

2) Anesthesiological conditions: fluid balance at end of surgery and 24 hours after surgery, hemodynamic values (cardiac output, stroke volume, systemic vascular resistance, heart rate, mean arterial pressure, heart rate), number of hypotensive episodes (MAP < 55 for more than 5, 10,15 minutes), vasopressor use.

3) Outcome variables: kidney function after surgery (creatinine level, and activation of RAAS system (plasma sodium (Na), aldosterone, ADH) in plasma and urine (Na, Creatinine, K, ureum, osmolality). Other: morbidity, respiratory, cardiovascular and neurologic events and surgical complications related to the procedure.

4) Whether surgeons can perceive a difference in the surgical conditions) created by a low central venous pressure and fluid restriction or a goal-directed therapy anesthetic regimen.

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

The liver is one of the best perfused organs. Hence, liver surgery is renowned for intraoperative hemorrhage and therefore its challenging hemodynamic and fluid management. Suggested interventions to reduce blood loss and morbidity almost all target at keeping a low central venous pressure (LCVP) and to restrict fluid infusion before and during hepatic resection. The short-term beneficial effects of LCVP on surgical operating conditions are at conflict with a large body of literature on goal-directed fluid therapy (GDFT) showing that optimization of dynamic preload parameters can half the morbidity related to high risk surgery. Therefore, in clinical practice it is unknown which of these two strategies to use during liver surgery.

Study objective

The aim of this double-blinded pilot randomized controlled trial (RCT) is to compare the effects of a conventional LCVP vs. a GDFT protocol in open liver surgery on surgical and anesthesiological conditions and its relation to outcome. Primary outcome parameter is intra-operative blood loss. Secondary outcomes are operating conditions as (subjectively) assessed by the surgeon, hemodynamic conditions, postoperative kidney function and activation of RAAS

system and morbidity rate.

Study design

a single-center patient- and surgeon-blinded pilot RCT

Intervention

Arm 1: LCVP group: During the exploration and parenchyma transection phase an absolute minimum of fluids are infused. CVP is aimed at < 5 mmHg. At the end of the resection phase, fluids are infused until an intra-operative fluid balance of 0-500+ is reached. Post-operatively, fluids will be infused according to the attending clinicians discretion.
Arm 2: GDFT group: Patients will be treated according to a classic goal-directed fluid regime aiming at stroke volume optimization. The GDFT protocol is continued post-operatively until discharge to the surgical ward.

Study burden and risks

Both fluid regimes are used standardly in practice as are the medications used. Extensive pre-clinical and clinical data are available. Thus, we expect no additional risk to be taken by patient. Patients receive standard of care regarding all other aspects.

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

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

Exclusion criteria

* 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)
* If no resection is performed

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-05-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-06-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	15-01-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL55086.018.15

Study results

Date completed:	29-06-2018
Results posted:	16-01-2019
Actual enrolment:	52

First publication
16-01-2019