The effect of an intraoperative, goal-directed volume protocol in abdominal surgery within an accelerated recovery program after surgery (Enhanced Recovery Program After Surgery- = ERAS-Program).

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON33620

Source
ToetsingOnline

Brief title
Improvement of Infusion therapy with Doppler in ERAS

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
colonic surgery

Research involving

Human

Sponsors and support

Primary sponsor: Charité - Universitätsmedizin Berlin
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: abdominal surgery, Doppler, ERAS, Volume

Outcome measures

Primary outcome

Primary Hypothesis:

In contrast to a liberal volume management strategy there is a difference in the amount of intravenously administered crystalloid and colloid fluid on the day of operation compared to a goal-directed volume protocol within an accelerated surgical recovery program (Enhanced Recovery After Surgery-Program = ERAS-Program).

Secondary outcome

Secondary Hypothesis:

The goal-directed perioperative fluid therapy reduces the intraoperative requirement for vasoactive drugs, the time to hospital discharge and the rate of postoperative complications (pain, delirium. infections, cardiac, pulmonary, gastrointestinal and renal dysfunction).

Study description

Background summary

Purpose of the study

The advent of the oesophageal doppler now gives the opportunity of measuring cardiac output on a minimally invasive basis in the perioperative and intensive care environment.
Up until now fluid administration has been guided by the optimisation of blood pressure, indirect preload parameters such as CVP and markers of adequate tissue perfusion such as urine production and lactate.

Since the blood pressure correlates poorly with cardiovascular flow, and because parameters such as CVP, urine output and lactate only change with severe fluid deficits this results in widely different amounts of intravenous fluids being administered.
It has been shown that excessive intravenous fluids adversely affect patients postoperatively in terms of impaired intestinal function and a higher risk of pulmonary complications [1].
On the other hand there are indications that an extremely restrictive volume regimen can also impair intestinal function and affect the well-being of the patient [2].

Using the oesophageal doppler one can treat the patient for the first time not only by applying a restrictive or liberal volume strategy but instead by optimising stroke volume using measurements acquired by minimally invasive means. Studies which have compared goal-directed volume administration with a liberal strategy have shown its superiority in many different surgical fields. This applies to traumatology, abdominal surgery and cardiac surgery. A table of the completed studies can be found in reference 1.

In abdominal surgery where expected blood loss was > 500ml a reduction in length of hospital stay and postoperative duration of paralytic ileus has been achieved by the use of a protocol with the oesophageal doppler. This study included urological, gynaecological and abdominal operations [3].
Wakeling et al. have succeeded in reducing the incidence of ileus and length of hospital stay using a goal-directed volume mangement strategy guided by oesophageal Doppler, too [4]. Noblett et al. performed the first trial in which the *liberal* group ended up getting the same amount of fluid as the goal-directed group showing the same results as Wakeling et al. [5].

The ERAS-Program aims to achieve a multi-modal improvement of peri-operative evidence-based treatment algorithms in order to accelerate patient recovery and minimise peri-operative problems [Wind, Polle, Br J Surg, 2006]. Thus far patient studies related to the ERAS project or the Fast-Track concept have shown a faster post-operative recovery but with similar or reduced morbidity to patients not taking part in the program. Patient safety is the main objective of the program. For this reason an international database has been setup to facilitate the process of quality control [7].

Part of the ERAS program is the optimisation of pre- and postoperative fluid management by avoiding extensive preoperative bowel irrigation. Patients can

drink up until 2 hours pre-operatively but postoperatively intravenous fluid administration is discontinued and an early resumption of oral intake is aimed for.

Up to this point all studies using the oesohageal doppler were single-center studies and were neither part of the ERAS program, nor integrated into a well-defined treatment pathway. At present there is no multi-center study which shows the superiority of a *goal-directed* versus a *liberal* fluid protocol within an ERAS framework.

Study objective

The goal of this study is to prove that there is a benefit in terms of post-operative outcome not only because of the multi-modal improvements in peri-operative fluid management through the ERAS program, but also by the use of a goal-directed fluid protocol.

Study design

Multicenter doubbelblind randomized trial.

Intervention

group 1: standard volume therapie

group 2: doppler guided volume therapie

Study burden and risks

Evaluation and consideration of the forseeable risks and disadvantages to the the study participants in contrast to the expected benefit for them and future patients. (Risk-benefit evaluation)

The risks of using the oesophageal doppler probe are seen as minimal. According to Deltex Medical the probe has thus far been used approximately 800,000 times and there has only once been a suspicion of an oesophageal injury. Previous studies have no indication of doppler-associated complications. By avoiding nasal insertion of the probe one avoids the risk of epistaxis and for the purposes of this study oral insertion of the probe will be used.

Against these minimal risks stand the findings of previous studies using the oesophageal doppler which have demonstrated a reduced rate of complications as well as a reduced length of ICU and hospital stay.

Ascertaining whether these desirable effects of Doppler guided volume therapy offer similar advantages to patients in the ERAS program over a liberal volume

strategy, is a goal of this study.

The small risk of probe placement is justified by the significant potential benefit.

Expected therapeutic benefit for the study participants (individual benefit for a single patient):

It has been shown in volume therapy studies in other patient populations that those guided by Doppler had an earlier stabilisation of their clinical condition and suffered a lower rate of complications, thereby allowing them earlier to be discharged home.

This proven effect in other populations is also the benefit expected to be seen in the Doppler guided group of this trial.

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

- Written patient consent
- Patients which
- undergo colonic resection above the peritoneal reflection.
- are treated within the context of an accelerated post-operative recovery program.

Exclusion criteria

Accommodation in an institute due to an official or judicial order
- No written consent from patient
- Unwillingness to allow storage and sharing of anonymised disease data in the context of the clinical study
- Simultaneous participation of the patient in another study or having been in a study which was terminated less than one week before.
- ASA >III
- Advanced disease of the oesophagus of nasopharyngeal cavity
-Operations in the area of the oesophagus or nasopharynx within the last 3 months
- Systemic steroid therapy
- Moderate or severe heart valve disease
- von Willebrands disease
- history of bleeding tendency
- Liver disease (Child B or C cirrhosis, MELD score >17 [9,10])
- Age <18 years
- Renal failure (serum creatinine >2.0mg/dL)
- Chronic heart failure NYHA III or IV
- history of intracranial haemorrhage
- Allergy to hydroxy-ethyl starch

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-04-2010
Enrollment:	14
Type:	Actual

Medical products/devices used

Generic name:	CardioQ (Oesofageal Doppler Monitor)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-11-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ISRCTN	ISRCTN94786070
CCMO	NL25714.068.09