ISRCTN94786070 https://doi.org/10.1186/ISRCTN94786070

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)

Submission date 04/02/2008	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 27/03/2008	**Overall study status** Completed	
Last Edited 11/08/2011	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
ERAS Doppler

Study objectives
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 (ERAS-Program).

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).

As of 03/11/2010 this record has been updated to include an extended anticipated end date; the initial anticipated end date of this trial was 01/02/2010.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Charité - University Medicine Berlin, approved on 4th December 2007

Study design
Prospective, randomised, double-blinded, two-arm multi-center trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Colonic resection above the peritoneal reflection

Interventions
Targeted-volume application guided by esophageal doppler vs conventional volume application

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Difference in the amount of intravenously administered crystalloid and colloid fluid on the day of operation

Secondary outcome measures
1. Reduction of the intraoperative requirement for vasoactive drugs
2. Time to hospital discharge
3. Rate of postoperative complications (pain, delirium. infections, cardiac, pulmonary, gastrointestinal and renal dysfunction). Patients will be monitored until they fulfill the hospital discharge criteria or up to 30th postoperative day.

Overall study start date
05/02/2008

Completion date
31/12/2011

Eligibility

Key inclusion criteria
1. Written patient consent
2. Patients who undergo colonic resection above the peritoneal reflection
3. Patients who are treated within the context of an accelerated post-operative recovery program

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
42

Key exclusion criteria

1. Accommodation in an institution due to an official or judicial order
2. No written consent from patient
3. Unwillingness to allow storage and sharing of anonymised disease data in the context of the clinical study
4. Simultaneous participation of the patient in another study or having been in a study which was terminated less than one week ago
5. American Society of Anaesthesiologists (ASA) classification >III
6. Advanced disease of the oesophagus of nasopharyngeal cavity
7. Operations in the area of the oesophagus or nasopharynx within the last 3 months
8. Systemic steroid therapy
9. Moderate or severe heart valve disease
10. von Willebrands disease
11. History of bleeding tendency
12. Liver disease (Child B or C cirrhosis, End-Stage Liver Disease [MELD] score >17)
13. Age <18 years
14. Renal failure (serum creatinine >2.0 mg/dL)
15. Chronic heart failure New York Heart Association (NYHA) class III or IV
16. History of intracranial haemorrhage
17. Allergy to hydroxy-ethyl starch

Date of first enrolment
05/02/2008

Date of final enrolment
31/12/2011

Locations

Countries of recruitment
Germany

Netherlands

Norway

Study participating centre
Charitéplatz 1
Berlin
Germany
10117

Sponsor information

Organisation
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/001w7jn25

Funder(s)

Funder type
University/education

Funder Name
Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin) (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration