

# 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)

<b>Submission date</b> 04/02/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 11/08/2011	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

### **Study type(s)**

Treatment

### **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(s)**

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

## **Key secondary outcome(s)**

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.

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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 or 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)

**ROR**

<https://ror.org/001w7jn25>

## Funder(s)

**Funder type**

University/education

**Funder Name**

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

## Results and Publications

Individual participant data (IPD) sharing plan

## **IPD sharing plan summary**

Not provided at time of registration