Improvement of fluid balance in patients undergoing surgery of the colon and rectum.

No registrations found.

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

Summary

ID

NL-OMON23916

Source
NTR

Brief title
Hemodynamic optimization in colorectal surgery

Health condition

Hemodynamic optimization, intestinal damage, ERAS, gastrointestinal disease.
Hemodynamische optimalisatie, intestinale schade, ERAS, gastrointestinale aandoeningen.

Sponsors and support

Primary sponsor: Maastricht University Medical Center +
Source(s) of monetary or material Support: Profileringsfonds Maastricht University Medical Center +

Intervention

Outcome measures

Primary outcome

Intestinal Fatty Acid Binding Protein (I-FABP) in plasma and urine.

Secondary outcome

1. C-reactive protein (CRP) in plasma;

2. Liver Fatty Acid Binding Protein (L-FABP) in plasma and urine;

3. CO2 gap (arterial pCO2 - pCO2 stomach lumen);

4. Postoperative complications.

Study description

Background summary

58 consecutive patients undergoing elective colorectal surgery are divided into two groups. The control group will receive standard care. The intervention group will receive standard care plus hemodynamic optimization based on in- or decrease of cardiac output. Between group differences are measured primarily by Intestinal Fatty Acid Binding Protein (I-FABP) in plasma and urine, an accurate marker of intestinal damage. Secundary outcome variables are plasma levels of CRP, plasma and urinary levels of Liver Fatty Acid Binding Protein (L-FABP, another marker of intestinal damage), and CO2 pressure in the stomach lumen (reflecting intestinal perfusion). We hypothesize that the intervention group will have less intestinal damage, improved intestinal perfusion and improved postoperative recovery compared to the control group.

Study objective

Hemodynamic optimization during and after colorectal surgery results in improved intestinal perfusion, sustained intestinal barrier and improved postoperative recovery.

Study design

1. Preoperative;

2. Every 15 minutes during surgery;

3. Every 60 minutes during the first 12 hours postoperatively;

4. Every 24 hours until discharge from hospital.

Intervention

Fluid and/or noradrenaline administration based on cardiac output in/decrease and mean

arterial pressure.

The control group will receive standard care. The intervention group will receive standard care plus hemodynamic optimization based on in- or decrease of cardiac output.

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Eligibility criteria

Inclusion criteria

1. All patients undergoing elective colorectal surgery with anastomosis;

2. Minimum age 18 years;

3. Giving informed consent.

Exclusion criteria

1. Other causes of intestinal damage: IBD, occlusive disease;

2. Steroid use;

3. Esophageal varices and other esophageal disease;

4. Aortic valve disease.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2010
Enrollment:	58
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-12-2009
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	NL2030
NTR-old	NTR2147
Other	MEC Academisch ziekenhuis Maastricht : 09-2-089
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A