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

Gepubliceerd: 22-12-2009 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23916

Bron
NTR

Verkorte titel
Hemodynamic optimization in colorectal surgery

Aandoening

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

Ondersteuning

Primaire sponsor: Maastricht University Medical Center +
Overige ondersteuning: Profileringsfonds Maastricht University Medical Center +

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. All patients undergoing elective colorectal surgery with anastomosis;

2. Minimum age 18 years;

3. Giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

2. Steroid use;

3. Esophageal varices and other esophageal disease;

4. Aortic valve disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2010
Aantal proefpersonen:	58
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-12-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2030
NTR-old	NTR2147
Ander register	MEC Academisch ziekenhuis Maastricht : 09-2-089
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A