Bacterial translocation, and intestinal permeability in patients undergoing open or laparoscopic total colectomy. - open, right side or left side first laparoscopically -

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We hypothesise that bacterial translocation is the least in open colectomy followed by laparoscopic colectomy starting the devascularisation on the left side followed by laparoscopic colectomy starting the devascularisation on the right side. The...

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

Samenvatting

ID

NL-OMON22017

Bron
Nationaal Trial Register

Verkorte titel
BactTrans

Aandoening

Bacterial translocation, total colectomy, proctocolectomy, intestinal permeability, devascularisation, laparoscopic colectomy.

Bacteriele translocatie, proctocolectomie, intestinale permeabiliteit, devascularisatie, laparoscopie

Ondersteuning

Primaire sponsor: Academic Medical Centre (AMC)
department of Surgery

Amsterdam
Overige ondersteuning: Academic Medical Centre (AMC)
department of Surgery
Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Intestinal permeability;
2. Amount of bacterial translocation

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Postoperative infectious complications such as pneumonia, sepsis, abscess, urinary tract infection, and cholangitis are mainly caused by the patient's own gut flora probably due to bacterial translocation. Bacterial translocation describes the passage of bacteria from the gastrointestinal tract to normally sterile tissues such as the mesenteric lymph nodes and other internal organs.
Objectives: To assess whether bacterial translocation occurs during laparoscopic total colectomy compared to open colectomy, and to determine whether the order of devascularisation matters with respect to bacterial translocation, and intestinal permeability.
Hypothesis: We hypothesise that bacterial translocation is the least in open colectomy followed by laparoscopic colectomy starting the devascularisation on the left side followed by laparoscopic colectomy starting the devascularisation on the right side.
The longer period of devascularisation results in an increased permeability and higher risk of bacterial translocation.
Patients and Methods: A total of 30 patients who are planned to undergo an open or laparoscopic total colectomy for inflammatory bowel diseases or familial adenomatous polyposis from AMC Amsterdam will be included in this study. After informed consent, patients that are planned to undergo a laparoscopic operation will be randomly assigned to 2 groups (right or left side first) using sealed envelopes. A third group will be a control group consisting of patients undergoing an open operation. Study parameters will be a) the concentration of polyethylene glycol (PEG) in the urine, b) the concentration of intestinal fatty acid binding protein (IFABP-c) in the urine, c) collection of mesenteric lymph nodes from the distal ileum and d) distal ileum full-thickness biopsies from the surgical resection specimen.

Doel van het onderzoek

We hypothesise that bacterial translocation is the least in open colectomy followed by laparoscopic colectomy starting the devascularisation on the left side followed by laparoscopic colectomy starting the devascularisation on the right side.
The longer period of devascularisation results in an increased permeability and higher risk of bacterial translocation.

Onderzoeksproduct en/of interventie

Devascularisation beginning left or right in case of laparoscopice colectomy. In case of open colectomy mobilization from lateral to medial

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age >18 years;
2. Patients planned for laparoscopic total colectomy for inflammatory bowel diseases or

familial adenomatous polyposis or patients undergoing subtotal colectomy;
3. Informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Antibiotics within a week prior to surgery (perioperative antibiotics are allowed);
2. Use of probiotic products 4 weeks before or during the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2006
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	23-07-2007
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	NL996
NTR-old	NTR1025
Ander register	:
ISRCTN	ISRCTN82467578

Resultaten

Samenvatting resultaten
n/a