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

No registrations found.

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

Summary

ID

NL-OMON22017

Source
Nationaal Trial Register

Brief title
BactTrans

Health condition

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

Bacteriele translocatie, proctocolectomie, intestinale permeabiliteit, devascularisatie, laparoscopie

Sponsors and support

Primary sponsor: Academic Medical Centre (AMC)
department of Surgery
Amsterdam
Source(s) of monetary or material Support: Academic Medical Centre (AMC)
department of Surgery

Amsterdam

Intervention

Outcome measures

Primary outcome

1. Intestinal permeability;
2. Amount of bacterial translocation

Secondary outcome

-

Study description

Background summary

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.

Study objective

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2006
Enrollment:	40
Type:	Anticipated

Ethics review

Positive opinion

Date:	23-07-2007
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	NL996
NTR-old	NTR1025
Other	:
ISRCTN	ISRCTN82467578

Study results

Summary results
n/a