

# Bacterial translocation, and intestinal permeability in patients undergoing open or laparoscopic total colectomy.

- open, right side or left side first laparoscopically -

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	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

## 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**

### **Public**

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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