

# Bacterial Translocation and intestinal permeability in patients undergoing open or laparoscopic total colectomy: open, right side or left side first laparoscopically

<b>Submission date</b> 23/08/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/08/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/09/2007	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

N/A

# Study information

## Scientific Title

## Acronym

BactTrans

## Study objectives

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.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Medical Ethics Committee AMC, Amsterdam on the 26th April 2006 (ref: MEC 06/045).

## Study design

Randomised, double-blind, parallel group trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied

Bacterial translocation and intestinal permeability

## Interventions

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

**Intervention Type**

Other

**Phase**

Not Specified

**Primary outcome measure**

1. Intestinal permeability, measured before, during and directly after surgery
2. Amount of bacterial translocation, measured before, during and directly after surgery

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/03/2006

**Completion date**

01/07/2008

**Eligibility****Key inclusion criteria**

1. Aged greater than 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

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Not Specified

**Target number of participants**

40

**Key exclusion criteria**

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

**Date of first enrolment**

01/03/2006

**Date of final enrolment**

01/07/2008

## **Locations**

### **Countries of recruitment**

Netherlands

### **Study participating centre**

**Academic Medical Centre (AMC)**

Amsterdam

Netherlands

1100 DD

## **Sponsor information**

### **Organisation**

Academic Medical Centre (AMC) (The Netherlands)

### **Sponsor details**

Department of Surgery

P.O. Box 22660

Amsterdam

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1100 DD

### **Sponsor type**

Hospital/treatment centre

### **Website**

<http://www.amc.uva.nl/>

### **ROR**

<https://ror.org/03t4gr691>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

### **Funder Name**

Academic Medical Centre (AMC) (The Netherlands)

# Results and Publications

## Publication and dissemination plan

Not provided at time of registration

## Intention to publish date

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration