

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

Submission date 23/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/08/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/09/2007	Condition category 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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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Not Specified

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)

ROR

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

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration