

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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| 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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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