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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 23/08/2007	**Overall study status** Completed	
Last Edited 26/09/2007	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 directely after surgery
2. Amount of bacterial translocation, measured before, during and directely 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
Netherlands
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