

Mechanical bowel preparation for elective colorectal surgery

Submission date 14/02/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 14/02/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/08/2009	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00288496

Protocol serial number
NTR575

Study information

Scientific Title

Acronym

POCON trial

Study objectives

Mechanical bowel preparation (MBP) is common practice in elective colorectal surgery. In recent literature the value of MBP is a subject of discussion. This non-inferiority, randomised study evaluates the value of MBP before colorectal surgery.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre randomised controlled parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Elective colorectal resections

Interventions

Patients were randomised before elective colorectal surgery to receive mechanical bowel preparation, consisted of 2-4 l of polyethylene glycol bowel lavage solution in combination with a fluid diet in one study arm. The other study arm received no mechanical bowel preparation and was allowed to have a normal meal on the day before operation.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Anastomotic failure, based on clinical suspicion (prolonged fever, abdominal pain, local or generalised peritonitis, leucocytosis) resulting in contrast radiography (X-ray or computed tomography [CT] scan) or laparotomy to confirm the diagnosis. No effort was made to screen for asymptomatic leakage.

Key secondary outcome(s)

1. Septic complications (wound infection, urinary tract infection, pneumonia, pelvic abscesses)
2. Fascia dehiscence
3. Death.

Completion date

19/02/2004

Eligibility

Key inclusion criteria

Elective colorectal resections with primary anastomosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Acute laparotomy
2. Laparoscopic colorectal surgery
3. Contraindications for the use of mechanical bowel preparation
4. A priori deviating (ileo) stoma
5. Age less than 18 years old

Date of first enrolment

15/04/1998

Date of final enrolment

19/02/2004

Locations

Countries of recruitment

Netherlands

Study participating centre

Fransiscus Gasthuis

Rotterdam

Netherlands

3045 PM

Sponsor information

Organisation

Ikazia Hospital (Netherlands)

ROR

<https://ror.org/01abkkw91>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Ikazia Hospital (Netherlands)

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	22/12/2007		Yes	No