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 [X] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number NCT00288496

Secondary identifying numbers 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

Secondary study design Randomised controlled trial

Study setting(s) Hospital

Study type(s) Treatment

Participant information sheet

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 measure

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.

Secondary outcome measures

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

Overall study start date 15/04/1998

Completion date 19/02/2004

Eligibility

Key inclusion criteria Elective colorectal resections with primary anastomosis

Participant type(s) Patient

Age group Not Specified

Sex Not Specified

Target number of participants 1433

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)

Sponsor details Montessoriweg 1 Rotterdam Netherlands 3083 AN

Sponsor type Hospital/treatment centre

ROR https://ror.org/01abkkw91

Funder(s)

Funder type Hospital/treatment centre

Funder Name Ikazia Hospital (Netherlands)

Results and Publications

Publication and dissemination plan Not provided at time of registration

Intention to publish date

IPD sharing plan summary

Not provided at time of registration

Study outputs

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