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Mechanical bowel preparation for elective colorectal surgery

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

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

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