

# Mechanical bowel preparation for elective colorectal surgery.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON20913

### Source

Nationaal Trial Register

### Brief title

POCON trial

## Sponsors and support

**Primary sponsor:** N/A

**Source(s) of monetary or material Support:** N/A

## Intervention

## Outcome measures

### Primary outcome

The primary endpoint of the study was anastomotic failure, which was based on clinical suspicion (prolonged fever, abdominal pain, local or generalized peritonitis, leucocytosis) resulting in contrast radiography (X-ray or CT-scan) or laparotomy to confirm the diagnosis. No effort was made to screen for asymptomatic leakage.

### Secondary outcome

Secondary endpoints were septic complications (wound infection, urinary tract infection, pneumonia, pelvic abscesses), fascia dehiscence and death.

# Study description

## Background summary

Mechanical bowel preparation (MBP) is common practice in elective colorectal surgery. In recent literature the value of MBP is subject of discussion. We conducted a multicenter, randomized study with the goal of comparing outcome of elective colorectal resections and primary anastomoses with and without mechanical bowel preparation in terms of anastomotic leakage and other septic complications.

Within the setting of a multicenter randomized trial, 1433 patients were randomized before elective colorectal surgery to receive either MBP or to have no MBP but a normal meal on the day before operation. The primary endpoint was anastomotic leakage. Secondary endpoints were septic complications (wound infection, urinary infection, pneumonia, pelvic abscesses), fascia dehiscence and death.

The incidence of anastomotic leakage was similar in both groups: 5.1% in patients without MBP versus 4.9% in patients with MBP ( $p=0.93$ ; 95% confidence interval for the difference (no MBP minus MBP) ranges from -2.3% to +2.7%). There were no significant differences in other septic complications, fascia dehiscence, or mortality. Fecal contamination, number of days until resumption of a normal diet, and duration of hospital stay were similar in both groups.

This study shows that elective colorectal surgery can be safely done without MBP. Therefore, MBP should be abandoned in elective colorectal surgery.

## Study objective

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

## Study design

N/A

## Intervention

Patients were randomized before elective colorectal surgery to receive mechanical bowel preparation, consisted of 2-4 liters 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.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

Elective colorectal resections with primary anastomosis.

### **Exclusion criteria**

1. Acute laparotomy;
2. laparoscopic colorectal surgery;
3. contraindications for the use of mechanical bowel preparation;
4. an a priori deviating (ileo) stoma;
5. age less than 18 years old.

## Study design

## Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-1998
Enrollment:	1433
Type:	Actual

## Ethics review

Positive opinion	
Date:	06-02-2006
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
NTR-new	NL531

**Register**

NTR-old

Other

ISRCTN

**ID**

NTR575

: N/A

ISRCTN85321563

## Study results

**Summary results**

Lancet. 2007 Dec 22;370(9605):2112-7

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oral presentation

POCON: Preoperatieve Colonvoorbereiding Onzin of Niet? Chirurgendagen, Nederlandse Vereniging voor Heelkunde, mei 2005.<br>

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Mechanical bowel preparation.

Colorectal themajaar 2005, closing congress, Nederlandse Vereniging voor Gastrointestinale chirurgie, Noordwijk, november 2005