

Bowel Preparation for elective Left-Sided Colonic Surgery

Submission date 26/02/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 26/02/2007	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 14/12/2007	Condition category Surgery	☐ Individual participant data ☐ Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr C van der Leeuw

Contact details
Atrium Medisch Centrum Heerlen
Chirurgie
Heerlen
Netherlands
6401 CX
+31 (0)64 847 7103
C.vanderLeeuw@student.unimaas.nl

Additional identifiers

Protocol serial number
NL14234.096.06

Study information

Scientific Title

Acronym

Study objectives

The objective of this study is to ascertain the best method of bowel preparation, prior to elective left-sided colonic surgery in terms of patient comfort and surgical efficacy. Sodium phosphate enemas (Coley) and bisacodyl (tablet and suppository) are to be compared. The occurrence of infections (wound, peritonitis) and anastomotic leaks will be monitored.

Null hypotheses are:

1. Patients in both groups experience pain and discomfort equally
2. The surgeon finds no difference in the condition of the left hemicolon intraoperatively
3. No difference in incidence of infection is found
4. No difference in incidence of anastomotic leaks is found

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the local ethics committee (Medisch Ethische Toetsingscommissie Atrium MC - Maaslandziekenhuis) on the 30th October 2006.

Primary study design

Interventional

Study design

Randomised, active controlled, parallel group, single blinded trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Bowel preparation, sodium phosphate enema, colonic surgery, bisacodyl

Interventions

Interventions in the bisacodyl group:

1. Evening before surgery (8 p.m.) - bisacodyl tablet 5 mg, four tablets, oral administration
2. Morning of surgery (6 a.m.) - bisacodyl suppository 10 mg, one suppository, rectal administration

Intervention in the Coley group:

1. Evening before surgery (8 p.m.) - Coley 133 ml, enema, rectal administration
2. Morning of surgery (6 a.m.) - Coley 133 ml, enema, rectal administration

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bisacodyl, sodium phosphate (Coley)

Primary outcome(s)

Questionnaires will be used to assess the opinions of patients and surgeons. The parameters are recorded in a five point scale.

Key secondary outcome(s)

The occurrence of infection (wound or peritonitis) and anastomotic leaks is determined by standard postoperative care and is established when the clinical diagnosis is made.

Completion date

01/06/2007

Eligibility**Key inclusion criteria**

The study population will consist of adult patients undergoing elective left-sided colonic surgery. Left-sided colonic surgery includes the following procedures:

1. Left hemicolectomy
2. Sigmoid resection
3. Low anterior resection
4. Hartmann procedure
5. Reconstruction of colostomy
6. Abdominoperineal resection by Miles

Procedures on the transverse colon will also be included as this can result intraoperatively in a left hemicolectomy. Reasons for surgery vary, examples are malignancy, diverticulitis, Crohns disease and ulcerative colitis.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

Exclusion criteria are:

1. Use of Klean-Prep
2. Contra-indications for use of bisacodyl and Colex
3. Emergency procedures

Date of first enrolment

06/11/2006

Date of final enrolment

01/06/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Atrium Medisch Centrum Heerlen

Heerlen

Netherlands

6401 CX

Sponsor information

Organisation

Atrium Medisch Centrum (The Netherlands)

ROR

<https://ror.org/0367sy10>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Atrium Medisch Centrum (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration