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# Bowel Preparation for elective Left-Sided Colonic Surgery

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

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
NL14234.096.06

## Study information

**Scientific Title**

**Acronym**

BP LSCS

## 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 (Colex) 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.

## Study design
Randomised, active controlled, parallel group, single blinded trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Bowel preparation, sodium phosphate enema, solonic 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 Colex group:
1. Evening before surgery (8 p.m.) - Colex 133 ml, enema, rectal administration
2. Morning of surgery (6 a.m.) - Colex 133 ml, enema, rectal administration

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Bisacodyl, sodium phosphate (Colex)

### 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/0367sye10

# 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