ISRCTN91751187 https://doi.org/10.1186/ISRCTN91751187

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
06/11/2006

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

Age group

Adult

Sex
Not Specified

Target number of participants
40

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)

Sponsor details
P.O. Box 4446
Heerlen
Netherlands
6401 CX

Sponsor type
Hospital/treatment centre

Website
http://www.atriummc.nl/

ROR
https://ror.org/0367sye10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Atrium Medisch Centrum (The 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