Bowel preparation for elective left-sided colonic surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22828

Source
Nationaal Trial Register

Brief title
BP LSCS

Health condition

The study population will consist of adult patients undergoing elective left-sided colonic surgery.
Left-sided colonic surgery includes the following procedures: left hemicolectomy, sigmoid resection, low anterior resection, Hartmann procedure, reconstruction of colostomy and 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, Crohn disease and ulcerative colitis.

Sponsors and support

Primary sponsor: None.
Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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.

Study description

Background summary

The objective of the randomized clinical trial "Bowel preparation for elective left-sided colonic surgery" is to compare sodium phosphate enemas (Colex) and bisacodyl (tablet and suppository) in terms of surgical efficacy and patient comfort.
The trial is single blind (surgeon is masked). Concealment of allocation is upheld. The primary outcomes (as described above) will be assessed through a 5-point questionnaire completed by surgeon and patient. Secondary to this the incidence of complications such as wound infection and anastomotic leaks will be monitored.

Study objective

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.

Study design

N/A

Intervention

Interventions in the bisacodyl group:

Evening before surgery, 8 PM - bisacodyl tablet 5 mg, 4 tablets, oral administration;

Morning of surgery, 6 AM - bisacodyl suppository 10 mg, 1 suppository, rectal administration.

Intervention in the Colex group:

Evening before surgery, 8 PM - Colex 133 ml, enema, rectal administration;

Morning of surgery, 6 AM - Colex 133 ml, enema, rectal administration.

Contacts

Public
Atrium MC Heerlen
Chirurgie
C. Leeuw, van der
Postbus 4446
Heerlen 6401 CX
The Netherlands
+31 6-48477103
Scientific
Atrium MC Heerlen
Chirurgie
C. Leeuw, van der
Postbus 4446
Heerlen 6401 CX
The Netherlands
+31 6-48477103

Eligibility criteria

Inclusion criteria

The study population will consist of adult patients undergoing elective left-sided colonic surgery. Left-sided colonic surgery includes the following procedures: left hemicolectomy, sigmoid resection, low anterior resection, Hartmann procedure, reconstruction of colostomy and 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, Crohn disease and ulcerative colitis.

Exclusion criteria

Exclusion criteria are:

1. Use of Klean-Prep;

2. Contra-indications for use of bisacodyl and Colex;

3. Emergency procedures.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-11-2006
Enrollment:	40
Type:	Actual

Ethics review

Positive opinion

Date:	28-01-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 30388
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL867
NTR-old	NTR881
CCMO	NL14234.096.06
ISRCTN	ISRCTN91751187
OMON	NL-OMON30388

Study results

Summary results
None.