Bowel preparation for elective left-sided colonic surgery.

Gepubliceerd: 28-01-2007 Laatst bijgewerkt: 15-05-2024

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)…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22828

Bron
Nationaal Trial Register

Verkorte titel
BP LSCS

Aandoening

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.

Ondersteuning

Primaire sponsor: None.
Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Exclusion criteria are:

1. Use of Klean-Prep;

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

3. Emergency procedures.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	06-11-2006
Aantal proefpersonen:	40
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	28-01-2007
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 30388
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
None.