Laxatives postoperative colorectal surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26932

Source
NTR

Brief title
LAPOCC

Health condition

Colorectal pathology, laxatives, colorectal surgery, postoperative ileus

Sponsors and support

Primary sponsor: Atrium Medisch Centrum Parkstad
Source(s) of monetary or material Support: Atrium Medisch Centrum Parkstad

Intervention

Outcome measures

Primary outcome

Time to gastrointestinal recovery, defined as time to first flatus or first defecation.

Secondary outcome

Appreciation of the laxatives being used, overall hospital stay and incidence of postoperative

complications (anastomotic leakage, wound infection, intra-abdominal abscess).

Study description

Background summary

Postoperative ileus is a well-known consequence of abdominal surgery which leads to prolonged hospital stay.
The objective of this trial is to compare time to gastrointestinal recovery after elective colorectal surgery between patients treated with a laxative versus patients treated with a placebo.

Study objective

Postoperative ileus is a well-known consequence of abdominal surgery which leads to prolonged hospital stay. Over the past years, the implementation of ERAS programs have lead to a reduction in postoperative hospital stay. The use of laxatives after colorectal surgery within these protocols is not yet evidence based.

The objective of this trial is to compare time to gastrointestinal recovery after elective colorectal surgery between patients treated with a laxative versus patients treated with a placebo.

Study design

N/A

Intervention

The laxatives being used in this trial are magnesiumoxide and bisacodyl. Patients will receive the laxative or the placebo for three days postoperatively, twice daily starting on the evening of surgery.

Contacts

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Eligibility criteria

Inclusion criteria

Patients planned for elective colorectal surgery will be included regardless of age, underlying pathology or co-morbidity. Procedures to be performed include right hemicolectomy, transversectomy, left-hemicolectomy, sigmoid resection, low anterior resection, polypectomy, abdominoperineal resection, and laparoscopic right or left hemicolectomy.

Exclusion criteria

1. Age <18 years;

2. Emergency procedures;

3. Contra-indications for the laxatives being used;

4. Lacking informed consent.

Study design

Design

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

Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2009
Enrollment:	215
Type:	Anticipated

Ethics review

Positive opinion

Date:	26-06-2009
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33165
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1773
NTR-old	NTR1883
CCMO	NL28256.096.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33165

Study results

Summary results
N/A