Laxatives postoperative colorectal surgery

Published: 23-06-2009
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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.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON33165

Source
ToetsingOnline

Brief title
LAPOCS

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
bowelpathology, colorectal pathology

Research involving
Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Colorectal surgery, Laxatives, Postoperative ileus

Outcome measures

Primary outcome

Time to gastrointestinal recovery, defined as time to first flatus and 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. 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.

Study objective

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

A single center prospective randomized placebo controlled trial.

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.

Study burden and risks

Participation is not associated with risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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, reconstruction ileostomy, reconstruction colostomy, laparoscopic right or left hemicolectomy

Exclusion criteria

Lacking informed consent, age <18 years, objection by treating physician, emergency procedures, contra-indications to the laxatives being used or the use of other types of laxatives than magnesiumoxide or bisacodyl.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Start date (anticipated):	15-06-2009
Enrollment:	215
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Bisacodyl
Generic name:	Bisacodyl
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Magnesium oxide

Generic name:	Magnesium Oxide
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	23-06-2009
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 26932
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2009-012700-53-NL
CCMO	NL28256.096.09
OMON	NL-OMON26932