Laxatives postoperative colorectal surgery.

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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…

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

Samenvatting

ID

NL-OMON26932

Bron
NTR

Verkorte titel
LAPOCC

Aandoening

Colorectal pathology, laxatives, colorectal surgery, postoperative ileus

Ondersteuning

Primaire sponsor: Atrium Medisch Centrum Parkstad
Overige ondersteuning: Atrium Medisch Centrum Parkstad

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age <18 years;

2. Emergency procedures;

3. Contra-indications for the laxatives being used;

4. Lacking informed consent.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd

Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2009
Aantal proefpersonen:	215
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33165
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A