

Effect of different treatment modalities in colorectal surgery on postoperative gastrointestinal motility.

Gepubliceerd: 26-06-2009 Laatste bijgewerkt: 18-08-2022

It can be hypothesized that fast track care and/or laparoscopy are associated with less exaggerated inflammatory response during and after surgery resulting in faster recovery of postoperative gastrointestinal motility.

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

Samenvatting

ID

NL-OMON23184

Bron

Nationaal Trial Register

Verkorte titel

LAFA-motility

Aandoening

- postoperative ileus
- postoperative motility/transit
- colorectal surgery
- laparoscopic surgery
- open surgery
- standard care
- fast track care

In Dutch:

- postoperatieve ileus
- postoperatieve gastrointestinale motiliteit/transit
- maag darm motoriek
- colorectale chirurgie
- laparoscopische chirurgie
- open chirurgie

- traditioneel herstel programma
- fast track herstel programma

Ondersteuning

Primaire sponsor: prof. dr. G.E.E. Boeckxstaens

Overige ondersteuning: fund= initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Postoperative gastrointestinal transit as measured by nuclear scintigraphy on POD1-3.

Toelichting onderzoek

Achtergrond van het onderzoek

Recent developments in large bowel surgery are the introduction of laparoscopic surgery and the implementation of multimodal fast track recovery programs. Both focus on a faster recovery and shorter hospital stay. Time until recovery of gastrointestinal motility is the major determinant of length of hospital stay.

The randomized controlled LAFA-site study (LAParoscopy and/or FASt track multimodal management versus standard care) was conceived to determine whether laparoscopic surgery, fast track perioperative care or a combination of both is to be preferred over open surgery with standard care with regard to postoperative gastrointestinal motility.

Patients eligible for segmental colectomy for malignant colorectal disease will be randomized to either:

1. Open colectomy with fast track;
2. Laparoscopic colectomy with standard care;
3. Laparoscopic surgery with fast track.

Primary outcome parameter is postoperative gastrointestinal transit. Secondary outcome parameters are signs and symptoms of postoperative gastrointestinal motility.

Doel van het onderzoek

It can be hypothesized that fast track care and/or laparoscopy are associated with less

exaggerated inflammatory response during and after surgery resulting in faster recovery of postoperative gastrointestinal motility.

Onderzoeksopzet

Postoperative day 1, 2, and 3 and for secondary outcomes every day until discharge.

Onderzoeksproduct en/of interventie

4 different treatment arms for patients eligible for segmental colectomy for malignant colorectal disease:

1. Laparoscopic surgery + fast track care*;
2. Laparoscopic surgery + standard care;
3. Open surgery + fast track care*;
4. Open surgery + standard care.

*Multimodal fast track perioperative recovery program which focusses on shorter hospital stay and faster recovery.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

The study population consists of patients eligible for segmental colectomy for malignant colorectal disease viz.

right and left colectomy and anterior resection.

Inclusion criteria are:

1. Age between 40 and 80 years;
2. Colorectal cancer including colon and recto sigmoid cancers;
3. ASA I-III.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior midline laparotomy;
2. ASA IV;
3. Laparoscopic surgeon not available;
4. Emergency surgery;
5. Planned stoma.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Factorieel
Toewijzing:	Gerandomiseerd
Blinding:	Dubbelblind

Controle: Actieve controle groep

Deelname

Nederland
Status: Werving gestart
(Verwachte) startdatum: 01-09-2005
Aantal proefpersonen: 80
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 26-06-2009
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1774
NTR-old	NTR1884
Ander register	METC AMC : 05/002
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A