

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

No registrations found.

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

Summary

ID

NL-OMON23184

Source

Nationaal Trial Register

Brief title

LAFA-motility

Health condition

- 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

Sponsors and support

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

Source(s) of monetary or material Support: fund= initiator = sponsor

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Signs and symptoms of postoperative gastrointestinal motility during admission; e.g. time to first bowel movement and oral solid intake.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-09-2005
Enrollment:	80
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

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results

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N/A