

Influence of laparoscopy and/or fast track multimodal management on gastrointestinal motility in comparison to open surgery and/or standard care.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25076

Source

NTR

Brief title

TRANSIT-study

Health condition

Colorectal cancer

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam

Source(s) of monetary or material Support: Internal research budget

Intervention

Outcome measures

Primary outcome

Gastrointestinal transit.

Secondary outcome

Clinical evaluation (passage of first stool, passage of first flatus, time till normal oral food-intake, time till discharge)

Intra -abdominal inflammatory status.

Study description

Background summary

Postoperative ileus (POI) is defined as delayed recovery of gastrointestinal motor function (motility) and is still considered an unavoidable consequence of abdominal surgery.

Aim:

To evaluate to what extend minimal invasive laparoscopic surgery and/or multimodal patient care (fast track) can prevent POI and/or improve post-surgical gastrointestinal motility if compared to open surgery and/or conventional patient care.

Patients and methods:

The current study protocol is an addendum on the LAFA protocol.

At the start and at the end of the surgical procedure peritoneal lavage fluid and blood samples are collected. Cytokine levels in these samples will be determined and cells will be isolated.

24 hours postoperative a labeled test-meal will be administered orally. Abdominal scans will be made 2, 24 and 48 hours after intake of the test-meal.

Study objective

That minimal invasive laparoscopic surgery and/or multimodal patient care (fast track) can prevent post operative ileus and/or improve post-surgical gastrointestinal motility compared to open surgery and/or conventional patient care.

Study design

N/A

Intervention

Laparoscopic surgery and fast track perioperative care.

Contacts

Public

Academic Medical Center (AMC),
P.O. Box 22660
J. Wind
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663170

Scientific

Academic Medical Center (AMC),
P.O. Box 22660
J. Wind
Meibergdreef 9
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5663170

Eligibility criteria

Inclusion criteria

1. Age between 40 and 80 years;
2. Colorectal cancer including colon and rectosigmoid cancers;
3. Informed consent.

Exclusion criteria

1. Prior midline laparotomy;
2. ASA IV;
3. Laparoscopic surgeon not available;
4. Prior upper and/or lower midline laparotomy;

5. Emergency colectomy;
6. Contraindications for epidural (coagulation disorders);
7. Planned stoma.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2005
Enrollment:	80
Type:	Actual

Ethics review

Positive opinion	
Date:	06-09-2005
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	NL238
NTR-old	NTR276
Other	: N/A
ISRCTN	ISRCTN26698501

Study results

Summary results

N/A