

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

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
20/12/2005	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
20/12/2005	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
18/11/2008	Cancer	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

NTR276

Study information

Scientific Title**Acronym**

TRANSIT-study

Study objectives

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.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from the local medical ethics committee

Study design

Randomised, double-blind, active controlled, parallel group trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Colorectal cancer

Interventions

Laparoscopic surgery and fast-track peri-operative care. 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 post-operative a labeled test-meal will be administered orally. Abdominal scans will be made 2, 24 and 48 hours after intake of the test-meal.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Gastrointestinal transit

Key secondary outcome(s)

1. Clinical evaluation (passage of first stool, passage of first flatus, time till normal oral food-intake, time till discharge)
2. Intra-abdominal inflammatory status

Completion date

01/07/2007

Eligibility

Key inclusion criteria

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

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Prior midline laparotomy
2. American Society of Anaesthesiologists (ASA) grade 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

Date of first enrolment

01/09/2005

Date of final enrolment

01/07/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre

Amsterdam

Netherlands

1100 DD

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Other

Funder Name

Internal funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration