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

Submission date
20/12/2005

Registration date
20/12/2005

Last Edited
18/11/2008

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr J. Wind

Contact details
Academic Medical Centre
P.O. Box 22660
Amsterdam
Netherlands
1100 DD
+31 (0)20 5663170
J.Wind@amc.uva.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Gastrointestinal transit

Secondary outcome measures
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

Overall study start date
01/09/2005

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

Age group
Adult

Sex
Both

Target number of participants
80

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)

Sponsor details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

Sponsor type
University/education

Website
http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Other

Funder Name
Internal funding

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration