

Peri-operative strategy in colonic surgery: Laparoscopy and/or Fast track multimodal management versus standard care (LAFA study)

Submission date 20/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 13/05/2009	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.lafa-trial.nl>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NTR222; ZonMw reference: 945-06-901

Study information

Scientific Title

Acronym

LAFA study

Study objectives

That laparoscopic surgery alone or in combination with fast track peri-operative care is to be preferred over open surgery with standard care in patients having segmental colectomy for malignant disease.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Received from local medical ethics committee

Study design

Multicentre 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

Laparoscopic surgery

Interventions

Laparoscopic surgery and fast track peri-operative care.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

1. Total post-operative hospital stay including readmission within 30 days
2. Quality of life measured by validated questionnaires (SF-36/Gigli) at two and four weeks after surgery
3. Medical and non-medical costs

Secondary outcome measures

1. Morbidity
2. Patient satisfaction measured by standardised questionnaires
3. Readmission percentage

Overall study start date

01/07/2005

Completion date

31/12/2008

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

400

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

01/07/2005

Date of final enrolment

31/12/2008

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

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

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