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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/12/2005	**Overall study status** Completed	
Last Edited 13/05/2009	**Condition category** Surgery	

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