ISRCTN79588422 https://doi.org/10.1186/ISRCTN79588422

# 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

**Registration date**
20/12/2005

**Overall study status**
Completed

**Last Edited**
13/05/2009

**Condition category**
Surgery

[ ] 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

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## Additional identifiers

**Protocol serial number**
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

### Primary study design
Interventional

### Study design
Multicentre randomised double-blind active controlled parallel group trial

### Study type(s)
Treatment

### 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(s)
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

### Key secondary outcome(s)
1. Morbidity
2. Patient satisfaction measured by standardised questionnaires
3. Readmission percentage

### 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

### 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
01/07/2005

### 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)

**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

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |