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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

#### Contact name

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#### Contact details

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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

#### Study design

Multicentre randomised double-blind active controlled parallel group trial

#### Primary study design

Interventional

#### 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