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

Contact name
Dr W.A. Bemelman

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

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