

Perioperative strategy in colonic surgery; LAparoscopy and/or FAst track multimodal management versus standard care (LAFA study).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28382

Source

NTR

Brief title

LAFA-study

Health condition

malignant colorectal disease

Sponsors and support

Primary sponsor: Academisch Medisch Centrum, Amsterdam

Source(s) of monetary or material Support: ZonMw projectnummer 945-06-901

Intervention

Outcome measures

Primary outcome

1. Total postoperative 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

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

Study description

Background summary

Background: Recent developments in large bowel surgery are the introduction of laparoscopic surgery and the implementation of fast track recovery multimodal programs. Both programs focus on faster recovery and shorter hospital stay.

Objectives: To determine whether laparoscopic surgery, fast track perioperative care or a combination of both is to be preferred over open surgery with standard care in patients having segmental colectomy for malignant disease.

Patients and

Methods: double blinded, multicenter trial with a 2 x 2 balanced factorial design. Patients eligible for segmental colectomy for malignant colorectal disease viz. right and left colectomy and anterior resection will be randomised to either open or laparoscopic colectomy, and to either standard care or the fast track program. This factorial design produces four treatment groups (a) open colectomy with standard care (b) open colectomy with fast track program (c) laparoscopic colectomy with standard care and (d) laparoscopic surgery with fast track program. Primary outcome measure are length of postoperative hospital stay including readmission within 30 days, quality of life two weeks after surgery, overall hospital costs.

Secondary outcome parameters are morbidity, patient satisfaction and readmission.

Data analysis: We anticipate a difference of 4 days between standard care and the fast track laparoscopic group. Based on a mean postoperative hospital stay of 9 +/- 2.5 days a group size of 400 patients (100 each arm) can reliably detect a minimum difference of 1 day between the four arms ($\alpha = 0.95$, $\beta = 0.8$). With 100 patients in each arm a difference of 10% in subscales of the SF-36 and social functioning can be detected.

Study objective

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

Intervention

Laparoscopic surgery and fast track perioperative care.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 40 and 80 years;
2. Colorectal cancer including colon and rectosigmoid cancers;
3. Informed consent.

Exclusion criteria

1. Prior midline laparotomy;
2. ASA 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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-07-2005
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion	
Date:	06-09-2005
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL185
NTR-old	NTR222
Other	: ZonMw projectnumber: 945-06-901
ISRCTN	ISRCTN79588422

Study results

Summary results

N/A