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

Gepubliceerd: 06-09-2005 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28382

Bron
NTR

Verkorte titel
LAFA-study

Aandoening

malignant colorectal disease

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum, Amsterdam
Overige ondersteuning: ZonMw projectnummer 945-06-901

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 (alfa = 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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

Laparoscopic surgery and fast track perioperative care.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2005
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-09-2005
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A