A prospective double-blind multi-centre trial: Laparoscopic versus open elective sigmoid resection in patients with symptomatic diverticulitis (Sigma-trial).

Gepubliceerd: 11-03-2007 Laatst bijgewerkt: 18-08-2022

That the laparoscopic approach should be preferred over the open procedure in cases of an elective sigmoid resection for symptomatic diverticulitis.

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

Samenvatting

ID

NL-OMON25115

Bron
Nationaal Trial Register

Verkorte titel
Sigma-trial

Aandoening

1. Diverticulitis;

2. sigmoid resection.

Ondersteuning

Primaire sponsor: VU medical center
Overige ondersteuning: VU medical center

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Morbidity;
2. Mortality;
3. Hospital stay;
4. Conversion rate.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Diverticulosis is a common disease in the western society with an incidence of 33-66%. 10-25% of these patients will develop diverticulitis. In order to prevent a high-risk acute operation it is advised to perform elective sigmoid resection after two episodes of diverticulitis in the elderly patient or after one episode in the younger (< 50 years) patient. Open sigmoid resection is still the gold standard, but laparoscopic colon resections seem to have certain advantages over open procedures. On the other hand, a double blind investigation has never been performed.

Methods/design:

Indication for elective resection is one episode of diverticulitis in patients < 50 years and two episodes in patient > 50 years or in case of progressive abdominal complaints due to strictures caused by a previous episode of diverticulits. The diagnosis is confirmed by CT-scan, barium enema and/or coloscopy.

It is required that the participating surgeons have performed at least 15 laparoscopic and open sigmoid resections. Open resection is performed by median laparotomy, laparoscopic resection is approached by 4 or 5 cannula. Sigmoid and colon which contain serosal changes or induration are removed and a tension free anastomosis is created. After completion of either surgical procedure an opaque dressing will be used, covering from 10 cm above the umbilicus to the pubic bone. Surgery details will be kept separate from the patient’s notes.

Endpoints are morbidity and mortality, duration of the operation, blood loss and conversion

percentage. Post operative recovery consists of return to normal diet, pain, analgesics, general health (SF-36 questionnaire) and duration of hospital stay.

Discussion:

The Sigma-trial is a prospective, multi-center, double-blind, randomized study to define the role of laparoscopic treatment in patients with symptomatic diverticulitis.

Doel van het onderzoek

That the laparoscopic approach should be preferred over the open procedure in cases of an elective sigmoid resection for symptomatic diverticulitis.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Open or laparoscopic sigmoid resection for diverticulitis.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients who were admitted for a conservatively treated episode of diverticulitis, who will therefore undergo an elective resection of the sigmoid;

2. The indication for elective resection is in patients <50 years after one episode of conservatively treated diverticulitis and in patients older than 50 years after two episodes of diverticulitis or in case of progressive abdominal complaints due to strictures caused by a previous episode of diverticulits;

3. The diagnosis diverticulitis is confirmed by CT-scan and/or barium enema and coloscopy;

4. Operation will take place at least after three months of the last attack of diverticulitis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Signs of acute diverticulitis;

2. Previous infra umbilical laparotomy;

3. Previous colorectal surgery;

4. No informed consent.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-01-2002
Aantal proefpersonen:	104
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-03-2007
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	NL904
NTR-old	NTR928
Ander register	:
ISRCTN	ISRCTN43911188

Resultaten

Samenvatting resultaten
N/A