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

No registrations found.

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

Summary

ID

NL-OMON25115

Source
NTR

Brief title
Sigma-trial

Health condition

1. Diverticulitis;

2. sigmoid resection.

Sponsors and support

Primary sponsor: VU medical center
Source(s) of monetary or material Support: VU medical center

Intervention

Outcome measures

Primary outcome

1. Morbidity;

2. Mortality;

3. Hospital stay;

4. Conversion rate.

Secondary outcome

1. Operating time;

2. Blood loss;

3. Painscore;

4. Return to normal diet;

5. Use of analgetics;

6. General health (SF-36).

Study description

Background summary

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.

Study objective

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

Study design

N/A

Intervention

Open or laparoscopic sigmoid resection for diverticulitis.

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. Signs of acute diverticulitis;

2. Previous infra umbilical laparotomy;

3. Previous colorectal surgery;

4. No informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-01-2002
Enrollment:	104
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-03-2007
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	NL904
NTR-old	NTR928
Other	:
ISRCTN	ISRCTN43911188

Study results

Summary results
N/A