Laparoscopic peritoneal lavage or resection for generalised peritonitis for perforated diverticulitis: a nationwide multicenter randomised trial

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Ethical review	-
Status	Recruitment stopped
Health condition type	Diverticular disorders
Study type	Interventional

Summary

ID

NL-OMON33349

Source
ToetsingOnline

Brief title
The Ladies

Condition

- Diverticular disorders
- Gastrointestinal therapeutic procedures

Synonym
perforated diverticulitis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: zonMW

Intervention

Keyword: anastomosis, Hartmann's procedure, perforated diverticulitis, peritoneal lavage

Outcome measures

Primary outcome

The following main outcomes will be assessed in this trial to compare the various strategies: Poor clinical outcome defined as a combined endpoint consisting of mortality, and major morbidity. Major morbidity includes any of the following events or conditions: reintervention, wound dehiscence/incisional hernia, abscess needing percutaneous drainage, urosepsis, myocardial infarction, renal failure and respiratory insufficiency. This will be the primary outcome in the lavage vs. resectional intervention comparison (LOLA). Stoma-free survival one year after initial surgery, is the only relevant and primary outcome for the comparison of the resectional strategies (DIVA).

Secondary outcome

Secondary endpoints are operating time, hospital stay, number of days alive and outside the hospital, incisional hernia, reinterventions within twelve months, health related quality of life, health care utilization and associated costs.

Study description

Background summary

Sigmoid resection for acute perforated diverticulitis is, regardless of

strategy, associated with substantial moribidity (up to 50%) and mortalitiy (15 to 25%). Just recently, excellent results were reported with laparoscopic lavage and drainage only, in patients with purulent peritonitis. Mortality and morbidity figures were less than 5%, and a colostomy was avoided in the majority of these patients. Potentially, this alternative brings a large gain in health and reduction of costs. Nevertheless, since sigmoidectomy is still considered the standard of care for perforated diverticulitis by most surgeons, implemention might be variabloe. If it is decided to perform a sigmoidectomy for perforated diverticulitis, the optimal strategy is still subject of debate.
The available literature suggests equality of sigmoid resection with or without anastomosis regarding postoperative mortality and morbidity. If a sigmoidectomy with anastomosis is done, a protective loop-ileostomy probably diminishes the number of anastomotic leakages and its complications. The available literature suggests that the likelihood of stoma closure is higher after resection, anastomosis and ileostomy (90%) in comparison to Hartmann's with colostomy (60%), but evidence is lacking.

Study objective

The first objective of this integrated trial (LOLA) is to determine whether laparoscopic lavage leads to better clinical outcomes compared to sigmoidectomy in patients with perforated diverticulitis with purulent peritonitis in terms of mortality and morbidity.
The second objective (DIVA) is to determine whether sigmoidectomy with anastomosis and ileostomy or sigmoidectomy with end-colostomy is the superior approach in patients with perforated diverticulitis with either purulent or feculent peritonitis in terms of stoma free survival.

Study design

The design of the study is randomised and multicenter. Patients presenting with signs of generalised peritonitis will have a CT-scan. If there is free intra-abdominal air with suspicion of perforated diverticulitis, the patient is potentially eligible for this study. If the in- and exclusion criteria are fulfilled, the patient will have a diagnostic laparoscopy to confirm the diagnosis. In case of purulent peritonitis the patients enters the LOLA arm of the study, in case of faecal peritonitis, the patient enters the DIVA arm of the study. Randomisation is performed during laparoscopy via the trial website. In case of purulent diverticulitis laparoscopic lavage is compared with either sigmoidectomy with colostomy or sigmoidectomy with anastomosis with defunctioning loop ileostomy (LOLA). The best evidence indicates that the latter two resectional strategies are equal in terms of morbidity and mortality in case of generalised peritonitis. For this reason a three way 2:1:1 randomisation is proposed. In case of faecal peritonitis or an overt perforation of the sigmoid, the patient will be randomised in the DIVA arm of this study. In this way all patients with perforated diverticulitis fulfilling

the in/exclusion criteria can be included in this study.

Intervention

In case of purulent diverticulitis laparoscopic lavage is compared with either sigmoidectomy with colostomy or sigmoidectomy with anastomosis with defunctioning loop ileostomy (LOLA arm). In case of faecal peritonitis or an overt perforation of the sigmoid, the patient will be randomised in the DIVA arm of this study to undergo either sigmoidectomy with colostomy or sigmoidectomy with anastomosis with defunctioning loop ileostomy.

Study burden and risks

(a) Patients participating in the LOLA arm of the trial undergoing laparoscopic lavage are at risk of not showing any clincical progress postoperatively and thus needing reoperation with sigmoidectomy. The benefit of this group is a possible reduced morbidity and mortality, the abscense of any stoma, a diminished hospital stay, lower incisional hernia rate and a higher quality of life.
(b) Patients in both arms of the trial treated with sigmoidectomy with primary anastomosis and ileostomy are at risk for reoperation as well, thereby undergoing Hartmann's procedure with end-colostomy, followed by a possible second stage operation for stoma removal.

Contacts

Public
Academisch Medisch Centrum

Postbus 22700
1100 DD Amsterdam
NL
Scientific
Academisch Medisch Centrum

Postbus 22700
1100 DD Amsterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient between 18 and 85 years of age
Free abdominal air on plain abdominal X-ray or CT-scan
Informed consent

Exclusion criteria

Dementia
Prior sigmoidectomy
Pelvic irradiation
Steroid treatment >20mg daily
Requirement of inotropics due to circulatory insufficiency

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-07-2010

Enrollment:	345
Type:	Actual

Ethics review

Not available

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
CCMO	NL28998.018.09