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# Diverticulitis - laparoscopic lavage versus resection (Hartman procedure) for acute diverticulitis with peritonitis: the DILALA trial

**Submission date**
28/08/2009

**Recruitment status**
No longer recruiting

**Registration date**
30/11/2009

**Overall study status**
Completed

**Last Edited**
20/01/2016

**Condition category**
Digestive System

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

## Plain English summary of protocol

Background and study aims
Diverticulosis is a common finding and is increasingly common with age. It has been suggested that about 50% of 60 year olds have diverticulosis. The most commonly occurring complication is inflammation, but even this is unusual. Even more unusual is a perforation of one diverticula, a potentially dangerous situation. Hinchey graded perforated diverticulitis into grade I - IV, where grade I and II refer to situations where the body manages to contain the perforation leading to an abscess formation within the abdominal cavity. This can be treated by antibiotics and in some cases also drainage. Perforated diverticulitis grade III means a situation with peritonitis and should be operated, as should grade IV where the peritonitis is caused by faeces in the abdominal cavity. In grade III the traditional operation has been an emergency procedure with resection of the perforated and inflamed part of the intestine and creation of a stoma, followed by antibiotic treatment and a high percentage of complications and re-operations, not only to remove the stoma and reconstruct the intestinal continuity. Recently there have been suggestions that in perforated diverticulitis a laparoscopic procedure with cleansing of the abdominal cavity ('lavage') using saline should suffice, and no resection of the inflamed intestine will be performed. However, as the condition is potentially life-threatening, high-quality trials comparing the traditional and the new type of surgery are needed.

Who can participate?
Patients with acute diverticulitis (no age limits, either sex).

What does the study involve?
Participants will be randomly allocated to either the traditional or the new type of surgery, with active follow-up of patients during the 12 months after the emergency surgery.

What are the possible benefits and risks of participating?
Potential benefits are that in almost all other types of abdominal disease treated by surgery, laparoscopy has been found to result in less pain, shorter recovery period, less blood loss and no difference regarding the main effect when compared to traditional open surgery. This goes for gall bladder disease, appendicitis, colon cancer and obesity surgery to mention some. The

possible down-side is of course that in this case, perforated diverticulitis, we do not know if the treatment is effective and safe. As far as is known today, through published series of cases treated by laparoscopic lavage but without controls, the results are good, and that is the basis for the ethical decision to allow the study. In some of the ongoing studies analysis of safety of the new treatment (laparoscopic lavage) has been performed, for example, halfway into the study, and in this study the external analysis group suggested to continue recruitment of patients.

Where is the study run from?
A number of hospitals in Sweden and Denmark

When is the study starting and how long is it expected to run for?
October 2009 to February 2014

Who is funding the study?
Sahlgrenska University Hospital (Sweden)

Who is the main contact?
Prof. Eva Haglind
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# Contact information

### Type(s)
Scientific

### Contact name
Prof Eva Haglind

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# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
DILALA 29442

# Study information

## Scientific Title
Diverticulitis - laparoscopic lavage versus resection (Hartman procedure) for acute diverticulitis with peritonitis: a multicentre intenrnational randomised open trial

## Acronym
DILALA

## Study objectives
Laparoscopy and peritoneal lavage for perforated diverticulitis Hinchey III results in fewer operations and complications and improved health related quality of life compared to open Hartman's resection.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. Sweden: Regionala Etikprövningsnämnden i Göteborg, 09/09/2009, ref: 378-09. Lead centre: Sahlgrenska University Hospital.
2. Denmark: De Videnskabsetiske komiteer i Region Hovedstaden, 21/09/2009, ref: CVR/SE nr 29190626, protocol: H4 2009-088. Lead centre: Herlev Hospital.

Norway lead centre still being set-up, ethics approval pending as of 09/10/2009.

## Study design
Multicentre international randomised 1:1 open trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (Danish and Swedish only)

## Health condition(s) or problem(s) studied
Perforated diverticulitis

## Interventions
1. Laparoscopy and peritoneal lavage and drainage: surgery consists of a laparoscopy of the abdomen with lavage using at least 3 litres of saline, until clear return fluid is achieved, after this a drain is placed in the abdominal cavity.
2. Open Hartman's resection: an open operation through a midline incision is performed. The

inflamed and perforated section of the colon is resected and the distal end closed with a colostomy constructed using the proximal end of the resected colon.

No set duration; dependent on the time taken for the above procedures. This treatment is only used in patients with an emergency situation of perforated diverticulitis.

Amended 10/05/2010:
All operations start with a diagnostic laparoscopy that is saved on DVD/server. If The abdomen is diagnosed as Hinchey III, the randomisation then takes place to either of the two operations 1 and 2 above.

Amended 11/01/2011:
As of 19/11/2010, the protocol has been changed 1) regarding prooperative work-up clarifying that a simple X-ray of the abdomen showing "air" is acceptable. 2) regarding lavage in the group that undergoes Hartmann's procedure. From this time no lavage in the Hartmann's procedure group.

## Intervention Type
Procedure/Surgery

## Primary outcome measure
Current primary outcome measures as of 17/12/2013:
Percentage of patients who were re-operated within 12 months

Previous primary outcome measures:
Number of operations within 12 months

## Secondary outcome measures
1. Re-admission: within 12 months from emergency diverticulitis
2. Post-operative infections: any point of time within 12 months of primary surgical procedure
3. Thrombosis: any point of time within 12 months of primary surgical procedure
4. Other complications: any point of time within 12 months of primary surgical procedure
5. Hernia: any point of time within 12 months of primary surgical procedure
6. Bowel obstruction: any point of time within 24 months of primary surgical procedure
7. Length of hospital stay: total time in hospital within 12 months
8. Quality of life: at discharge from hospital, at 6 and 12 months after primary emergency surgery
9. Health economy: at 12 and 24 months after primary surgical procedure
10. Mortality: within 28 days and 12 months after primary surgical procedure
11. Permanent stoma: at 12 months those with a persistent stoma are judged as 'permanent'
12. Re-admissions and re-operations: within 24 months; as found in hospital/national registries with appropriate International Classification of Diseases (ICD) coding

Added 17/12/2013:
13. Total number of operations in test and control groups, respectively, within 12 and 24 months

## Overall study start date
01/10/2009

## Completion date
01/02/2014

# Eligibility

### Key inclusion criteria
1. Patients with acute diverticulitis (no age limits, either sex)
2. Intra-abdominal fluid or gas on computed tomography (CT)
3. Decision by the surgeon to perform emergency surgery
4. Possible to operate in regard to concomitant disease
5. Informed consent

Amended 10/05/2010:
The ethical committees have given permission for patients who are unable to give informed consent due to the diverticulitis, to be included until such time postoperatively when they can be duly informed and then give an informed consent or withdraw the presumed consent.

### Participant type(s)
Patient

### Age group
Other

### Sex
Both

### Target number of participants
40 + 40

### Key exclusion criteria
Current exclusion criteria as of 30/06/2011:
1. Exclusion criteria:
1.1. Not possible to operate due to concomitant disease
1.2. Participation in other randomized trials in conflict with the protocol and end-points of the DILALA trial
2. Randomization: criteria
2.1. Perforated diverticulitis Hinchey grad III at diagnostic laparoscopy
3. Exclusion from randomization: criteria
3.1. Hinchey grade I - II at laparoscopy i.e. no free fluid/pus in the abdomen  no further surgical procedure
3.2. Hinchey grade IV at laparoscopy, i.e. gross faecal contamination will be converted to open surgical procedure with resection and stoma formation
3.3. Other pathology than perforated diverticulitis, for example perforated appendicitis or stomach ulcer.
4. Exclusion after randomization
4.1. Withdrawn consent
4.2. Cancer diagnosed in resected specimen (only possible in randomised to Hartmanns procedure)
4.3. Cancer diagnosed at colonoscopy after initial episode
5. Intention to treat
5.1. All patients randomised in accordance with randomization criteria and not excluded correctly after randomization (criteria for this see above) will be analysed in group of randomization. This means that patients randomized to laparocopic lavage and converted to open surgery will be analysed in the 'laparoscopic lavage group'

Previous exclusion criteria:
1. Patients not possible to operate due to concomitant disease
2. Hinchey grade I - II at laparoscopy i.e. no free fluid - no further surgical procedure
3. Hinchey grade IV at laparoscopy, i.e. gross faecal contamination will be converted to open surgical procedure with resection and stoma formation
4. Participation in other randomised trials in conflict with the protocol and end-points of this trial

### Date of first enrolment
01/10/2009

### Date of final enrolment
01/02/2014

## Locations

### Countries of recruitment
Denmark

Norway

Sweden

### Study participating centre
**Sahlgrenska University Hospital**
Göteborg
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## Sponsor information

### Organisation
Sahlgrenska University Hospital (Sweden) - Department of Surgery

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### Sponsor type
Hospital/treatment centre

### Website

http://www.sahlgrenska.se

**ROR**
https://ror.org/04vgqjj36

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
Sahlgrenska Universitetssjukhuset

**Alternative Name(s)**
Sahlgrenska University Hospital, SU

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
Universities (academic only)

**Location**
Sweden

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 01/08/2011 | | Yes | No |
| Results article | results | 02/02/2016 | | Yes | No |