

Scandinavian Diverticulitis Trial – SCANDIV

a randomized prospective multicenter trial

Laparoscopic lavage vs. primary resection as treatment for perforated diverticulitis

Patient registration form (3pages)

Hospital:

Patient no. according to randomisation:

Year of birth (also not included pat.):

Male Female

Surgeon`s name:

Admission: date: / -20 approximate time: : min **Weight :** kg
Symptom debut: date: / -20 approximate time: : min **Height :** cm

ASA score 1 2 3 4 5
degree of systemic disease: 1 =none 2= mild 3 =severe 4 =life threatening 5 =moribund patient

Previous diverticulitis: None Single Multiple

Previous abdominal surgery: None Single Multiple

If yes: Year(s) _____ Cause _____ Type of surgery _____

Co-morbidity

None

Ischemic heart disease/ Heart failure	<input type="checkbox"/>	Immunodeficiency, Chronic Hepatitis	<input type="checkbox"/>
Chronic obstructive lung disease /Asthma	<input type="checkbox"/>	Cigarette Smoking (>10 /day)	<input type="checkbox"/>
Uraemia demanding dialysis	<input type="checkbox"/>	Anti-inflammatory medication	<input type="checkbox"/>
Insulin treated diabetes	<input type="checkbox"/>	(steroids, anti-TNF)	<input type="checkbox"/>
Active malignancy	<input type="checkbox"/>	Alcoholism, Drug abuse	<input type="checkbox"/>

Other co-morbidity Type: _____

Comments: _____

Inclusion criteria

Clinical suspicion of perforated diverticulitis indicating surgery	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Free air and diverticulitis findings on CT scan	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Age above 18 years	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Patient tolerates general anaesthesia	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Written consent given	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

Exclusion criteria

Pregnant	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Bowel obstruction	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

Randomization (the patient is not to be informed about the result of randomization before the operation)

Patient meets criteria for inclusion: Yes No
Patient included: Yes No
Reason if no: _____
Randomized to: Primary resection Laparoscopic peritoneal lavage

Antibiotic treatment

Start of antibiotic treatment: preoperative peroperative postoperative
Type of antibiotics given: _____
Comments: _____

Peroperative phase

Operation start: date: dd/mm -20 time: h : min
Operation end: date: dd/mm -20 time: h : min

Hinchey grade of peritonitis:

Hinchey grade: I IIa IIb III IV
Comments: _____

Grade	Definition
I	Pericolic abscess
IIa	Distant abscess amendable to percutaneous drainage
IIb	Complex abscess associated with fistula
III	Generalized purulent peritonitis
IV	Faecal peritonitis

Amount of saline used for rinsing of the abdominal cavity (minimum 4 litres): _____

Procedure: Hartmann`s procedure
Resection and anastomosis Defunctioning stoma Yes No
Laparoscopic Peritoneal lavage
Other

Reason if not operated according to randomization: _____

Peroperative complications: Yes No

If yes, specify: _____

Epidural anaesthesia: Yes No

Estimated blood loss: _____ ml

Most experienced surgeon on the operation team:

Colorectal surgeon:
Gastroenterological surgeon:
General surgeon:
Resident

Postoperative phase

Duration of intensive care: days (excluded standard postoperative observation)

Number of blood units given:

Postoperative complications:

- None**
- Superficial wound infection Heart and lung complications
- Deep (intra abdominal) infection Stoma complications
- Secondary peritonitis Urinary tract infection
- Bleeding Deep vein thrombosis/thromboembolus
- Pneumonia Cerebrovascular event
- Other specify: _____

Reoperations: Yes No

Reason and type of reoperation: _____

Maximum postoperative CRP (mg/L): **Minimum Haemoglobin (g/dL) :**

Discharge date: dd/mm -20

Discharged to: Home Other hospital Nursing home Rehabilitation centre
Other _____

Clavien-Dindo Classification of Surgical Complications:

Clavian score I II IIIa IIIb IVa IVb V

Grade	Definition
Grade I	Any deviation from the normal course without the need for pharmacological treatment or surgical, endoscopic and radiologic interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
III a	Intervention not under general anaesthesia
III b	Intervention under general anaesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
IV a	Single organ dysfunction (including dialysis)
IV b	Multiorgan dysfunction
Grade V	Death of a patient

*Brain haemorrhage, ischemic stroke, subarachnoidal bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.