Laparoscopic peritoneal lavage or resection for generalised peritonitis for perforated diverticulitis: a nationwide multicenter randomised trial (The Ladies Trial).

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Laparoscopic lavage for purulent peritonitis for perforated diverticulitis leads to a 15% reduction in the combined endpoint of major morbidity and mortality, compared to resection. Resection with primary anastomosis leads to a 22% reduction in...

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

Samenvatting

ID

NL-OMON27671

Bron
Nationaal Trial Register

Verkorte titel
The Ladies Trial

Aandoening

Diverticulitis, Diverticular disease, Divertikelziekte, Divertikels, Hartmann, Hartmann's procedure, Primary anastomosis, Primaire anastomose, Laparoscopic lavage, Laparoscopische lavage, Hinchey III, Hinchey IV, Purulent peritonitis, Faecal peritonitis, Purulente peritonitis, Faecale peritonitis

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Initiator: Prof. Dr. W.A. Bemelman

Erasmus Medical Center, Rotterdam,
Initiator: Prof. Dr. J.F Lange
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. (LOLA-arm) 1 year combined endpoint of major morbidity and mortality for patients randomised between laparoscopic lavage or open resection;
2. (DIVA-arm) 1 year stoma free survival for patients randomised between Hartmann's procedure or sigmoidresection with primary anastomosis.

Toelichting onderzoek

Achtergrond van het onderzoek

This nationwide, multicenter, randomised trial aims to prove the safety and effectiveness of laparoscopic lavage as a treatment for generalised purulent peritonitis for perforated diverticulitis. Secondly, this study wants to prove that sigmoidresection with primary anastomosis with or without protetective loop-ileostomy is the favored option for patients with generalised peritonitis for perforated diverticulitis, since this leads to a higher stoma-free survival.

Doel van het onderzoek

Laparoscopic lavage for purulent peritonitis for perforated diverticulitis leads to a 15% reduction in the combined endpoint of major morbidity and mortality, compared to resection.
Resection with primary anastomosis
leads to a 22% reduction in the 1 year stoma-free survival in patients with either purulent or faecal peritonitis for perforated diverticulitis, compared to the Hartmann's procedure.

Onderzoeksopzet

Follow-up to all patients is 12 months.

Onderzoeksproduct en/of interventie

All included patients are examined by laparoscopy. Patients with purulent peritonitis are randomised between laparoscopic lavage, open sigmoidresection with primary anastomosis with or without protective loop-ileostomy and Hartmann's procedure in ratio 2:1:1. This group

is followed over the course of a year to determine the combined endpoint of mortality and major morbidity.

Patients with faecal peritonitis are randomised between the sigmoidresection with primary anastomosis with or without protective loop-ileostomy and Hartmann's procedure in ration 1:1. This group is followed over the course of a year to determine the stoma-free survival.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Clinical suspicion for perforated diverticulitis;

2. Free abdominal gas on CT-scan or plain abdominal X-ray OR peritonitis with diffuse gas or fluid on CT-scan;

3. Patient between 18-85 years;

4. Informed Consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Prior Sigmoidresection;

2. Dementia;

3. Shock: requirement of inotropics for circulatory stabilisation;

4. Steroid treatment >20mg/day;

5. Pelvic irradiation.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2010
Aantal proefpersonen:	283
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	29-09-2009
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	NL1920
NTR-old	NTR2037
Ander register	ZonMW : 80-82310-97-10036
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Swank HA, Vermeulen J, Lange JF, et al. The ladies trial: laparoscopic peritoneal lavage or resection for purulent peritonitis and Hartmann's procedure or resection with primary anastomosis for purulent or faecal peritonitis in perforated diverticulitis (NTR2037). BMC Surg 2010; 10: 29. (Studie protocol)