A prospective double-blind multi-centre trial: laparoscopic versus open elective sigmoid resection in patients with symptomatic diverticulitis

Submission date	Recruitment status No longer recruiting	Prospectively registered		
11/04/2007		[X] Protocol		
Registration date	Overall study status	Statistical analysis plan		
11/04/2007	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
05/01/2009	Surgery			

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number NTR928

Study information

Scientific Title

Acronym

Sigma-trial

Study objectives

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

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the medical ethics committee of the VU Medical Centre on the 19th September 2003 (ref: 2003/109)

Study design

Randomised, double blinded, active controlled, parallel group, multicentre trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diverticulitis, sigmoid resection

Interventions

Open or laparoscopic sigmoid resection for diverticulitis.

Data is collected at the following times:

- 1. Pre-operative at the outpatient clinic: 36-item Short Form Health Survey (SF-36), Visual Analogue Scale (VAS)-pain score, medication, history and medical workup concerning diverticulitis
- 2. Peri-operative data (operating time, blood loss, conversion, etc.)
- 3. Post-operatively, there are short term data and long term data:
- 3.1. Short term: return to diet, minor and major complications (primary endpoint), pain, analgesics; all during hospital stay
- 3.2. Long term follow up, we see patients at the outpatient clinic at six weeks and six months post operative. They fill out an SF-36 questionnaire (general health) and VAS-pain score; we note late complications and use of analgesics.

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome(s)

- 1. Morbidity (measured post-operatively)
- 2. Mortality (measured post-operatively)
- 3. Hospital stay (measured post-operatively)
- 4. Conversion rate (measured peri-operatively)

Key secondary outcome(s))

- 1. Operating time (measured peri-operatively)
- 2. Blood loss (measured peri-operatively)
- 3. Pain score (VAS) (measured pre-operatively, post-operatively and at six weeks and six months post-operatively)
- 4. Return to normal diet (post-operatively)
- 5. Use of analgesics (post-operatively and at six weeks and six months post-operatively)
- 6. General health (SF-36) (measured pre-operatively, post-operatively and at six weeks and six months post-operatively)

Completion date

01/01/2008

Eligibility

Key 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 less than 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 diverticulitis
- 3. The diagnosis diverticulitis is confirmed by computed tomography (CT)-scan and/or barium enema and coloscopy
- 4. Operation will take place at least after three months of the last attack of diverticulitis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Αll

Key exclusion criteria

- 1. Signs of acute diverticulitis
- 2. Previous infra-umbilical laparotomy
- 3. Previous colorectal surgery
- 4. No informed consent

Date of first enrolment

Date of final enrolment 01/01/2008

Locations

Countries of recruitment

Netherlands

Study participating centre
Vrije Universiteit Medical Centre (VUMC)
Amsterdam
Netherlands
1007 MB

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (The Netherlands)

ROR

https://ror.org/00q6h8f30

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Vrije University Medical Centre (VUMC) (The Netherlands)

Results and Publications

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?
Results article	results:	01/01/2009		Yes	No
Protocol article	Protocol:	03/08/2007		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes