ISRCTN43911188 https://doi.org/10.1186/ISRCTN43911188

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

Submission date
11/04/2007

Recruitment status
No longer recruiting

Registration date
11/04/2007

Overall study status
Completed

Last Edited
05/01/2009

Condition category
Surgery

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.sigmatrial.nl

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/01/2002

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

Age group
Adult

Sex
Both

Target number of participants
104

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
01/01/2002

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)

Sponsor details

Department of Surgery
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Sponsor type
Hospital/treatment centre

Website
http://www.vumc.nl/english/#http://www.vumc.nl/english/

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vrije University Medical Centre (VUMC) (The Netherlands)

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:	03/08/2007		Yes	No
Results article	results:	01/01/2009		Yes	No