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Laparoscopic-assisted or -facilitated sigmoidectomy for diverticulitis? A prospective randomised trial

Submission date	Recruitment status	[ ] Prospectively registered
27/12/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
02/04/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
02/04/2008	Digestive System	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
04004

Study information

Scientific Title

Study objectives
Laparoscopic assisted and facilitated sigmoidectomy result in equivalent postoperative outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the University of Cologne (ref: 04004)

Primary study design
Interventional

Study design
Prospective, unblinded, single-centre, randomized controlled trial.

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diverticulitis of the sigmoid colon

Interventions
Group 1: Laparoscopic assisted sigmoidectomy with extraction of the specimen via a 5 cm mini-incision in the lower left abdomen
Group 2: Laparoscopic facilitated sigmoidectomy with laparoscopic mobilisation of the sigmoid colon and conventional resection and anastomosis via a 10-12 cm transverse suprapubic incision

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Cumulative consumption of piritramid administered over 96 hours using a Patient Controlled Analgesia (PCA) protocol

Key secondary outcome(s)
1. The course of postoperative analgesic consumption over 7 days.
2. Amount of postoperative pain and fatigue. Pain was evaluated daily using a visual analogue scale. It was documented once daily starting on the day prior to surgery and then in the morning of each postoperative day. Fatigue was also measured using a visual analogue scale. Fatigue was measured preoperatively and on days 3, 5, 7, 21 and 42 after surgery.
3. Resumption of bowel activity - the time-point of first passage of flatus and the first passage of stool were documented.
4. Pulmonary function, assessed by measuring Forced Vital Capacity (FVC) and forced expiratory volume in 1 second (FEV1) with a mobile spirometer (Renaissance®, Nellcor Puritan Bennett). Pulmonary function was measured the day before surgery and on days 2, 3, 5, and 7. The

postoperative data on pulmonary function for each patient were calculated in relation to the preoperative values.
5. Quality of life, measured using the Gastrointestinal Quality of Life Index. It was determined preoperatively, and on days 7, 21, 42 and after one year after surgery.
6. Satisfaction with the cosmetic result, evaluated using the Body Image Questionnaire. The evaluation was performed at one year after surgery.

Completion date
01/10/2005

Eligibility

Key inclusion criteria
Indication for elective sigmoidectomy for diverticulitis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Proven or suspected malignancy
2. Prior major abdominal surgery performed through a midline incision
3. Diverticulitis in association with fistula and abscesses (if diagnosed preoperatively)

Date of first enrolment
01/06/2004

Date of final enrolment
01/10/2005

Locations

Countries of recruitment
Germany

Study participating centre
Clinic of Abdominal and General Surgery
Mainz
Germany
55131

Sponsor information

Organisation
Individual Sponsor (Germany)

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leverkusen General Hospital, University of Cologne (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration