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# Totally laparoscopic versus conventional ileoanal pouch procedure: A randomised controlled trial

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 08/12/2004 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 24/01/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 04/10/2017 | Digestive System | |

**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**
KSC 01/2004

## Study information

**Scientific Title**
Totally laparoscopic versus conventional ileoanal pouch procedure: A randomised controlled trial

## Acronym
LapConPouch-Trial

## Study objectives
Restorative proctocolectomy is increasingly being performed minimal invasively but a totally laparoscopic technique has not yet been compared to the standard open technique in a randomized study. The trial will answer the question whether there is indeed an advantage in the laparoscopic group in regard to blood loss and the need for blood transfusions. Moreover, it will generate data on the safety and potential advantages and disadvantages of the minimally invasive approach.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised controlled trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Proctocolectomy

## Interventions
This is an intra-operatively randomised, controlled single centre trial of patients with familial polyposis (FAP) or ulcerative colitis (UC) who undergo primary elective restorative proctocolectomy. It is designed as a two-group parallel superiority study. The randomisation will be performed after induction of anaesthesia. The pre and postoperative treatment and assessment is kept equal in both groups to minimise bias.

80 laparoscopic versus 80 conventional ileoanal pouch.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
The primary objective of this study is to compare the totally laparoscopic with the conventional approach in regard to intraoperative blood loss and need for perioperative blood transfusions (within first 24 hours after surgery). We hypothesise that intraoperative blood loss and the need for peri-operative blood transfusions are significantly higher in the conventional group.

## Key secondary outcome(s))
A set of surgical and non-surgical parameters related to the operation will be analysed as secondary objectives. These will include operative time, complications, postoperative pain, lung function, postoperative length of hospital stay, a cosmetic score and pre-and postoperative

quality of life. Moreover an appraisal of patients as well as of physicians concerning the relevance of various outcome parameters will be evaluated as part of an additional scientific project in order to create a basis for further relevant research questions.

### Completion date
30/09/2008

## Eligibility

### Key inclusion criteria
Hospitalised patients of the Department of General surgery, Visceral surgery, Trauma surgery and Outpatient Clinic of the University of Heidelberg, Medical School, who are planned for an elective restorative proctocolectomy either for familial polyposis or for ulcerative colitis. 160 patients (80 laparoscopic vs 80 conventional ileoanal pouch) will be enrolled in order to recruit the 65 evaluable patients per group for the primary endpoint.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Sex
All

### Key exclusion criteria
Not provided at time of registration

### Date of first enrolment
01/09/2004

### Date of final enrolment
30/09/2008

## Locations

### Countries of recruitment
Germany

### Study participating centre
**Heidelberg University**
Im Neuenheimer Feld 110
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# Sponsor information

**Organisation**
University of Heidelberg Medical School (Germany)

**ROR**
https://ror.org/038t36y30

# Funder(s)

**Funder type**
University/education

**Funder Name**
University of Heidelberg Medical School

# 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 | 01/08/2013 | | Yes | No |
| Protocol article | protocol | 24/11/2006 | | Yes | No |