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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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.

Overall study start date
01/09/2004

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

Age group
Adult

Sex
Both

Target number of participants
160

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)

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Sponsor type
University/education

ROR
https://ror.org/038t36y30

Funder(s)

Funder type
University/education

Funder Name
University of Heidelberg Medical School

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	24/11/2006		Yes	No
Results article	results	01/08/2013		Yes	No