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Colon J-Pouch (CJP) versus transverse coloplasty pouch (TCP) after low anterior resection in rectal cancer: a randomised controlled trial

Submission date 08/12/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 24/01/2005	**Overall study status** Completed	
Last Edited 15/09/2008	**Condition category** Cancer	

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 01/2002

Study information

Scientific Title

Acronym
POUCH - Trial

Study objectives
The straight colo-anal anastomosis after LAR/TME is often associated with poor functional results in the first two years. With the Colon J-Pouch (CJP) better early post-operative results could be achieved, however, late evacuation problems occurred. Therefore, the transverse coloplasty pouch (TCP) was developed, which showed good functional results in the early and late post-operative period in phase I/II trials. The purpose of this trial is to compare the CJP with the TCP in terms of surgically related mortality and morbidity as well as functional outcome.

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
Rectal cancer

Interventions
Patients with rectal cancer of the lower two thirds, eligible for low anterior resection (LAR) with total mesorectal excision (TME).

Patients will be randomized intraoperatively to either the Colon J-Pouch or Transverse Coloplasty group if they are eligible for both. Postoperative follow-up will assess the safety of TCP and CJP after LAR/TME, including postoperative mortality, morbidity and functional results. Functional outcome will be monitored for 24 months. Each participant has to answer questionnaires about their neorectal function after certain time periods.

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))

Not provided at time of registration

Completion date
30/06/2005

Eligibility

Key inclusion criteria
For inclusion in this trial, patients have to be eligible for low anterior resection with TME due to a tumour of the lower rectum (potential R0 resection). Presumed preservation and a normal function of the rectal sphincter with faecal continence pre-operatively are mandatory.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/06/2002

Date of final enrolment
30/06/2005

Locations

Countries of recruitment
Germany

Study participating centre
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 (Germany)

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	Functional results:	01/08/2005		Yes	No
Results article	Early results:	01/10/2008		Yes	No