

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 24/01/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/09/2008	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof Markus W Buechler

Contact details

Im Neuenheimer Feld 110

Heidelberg

Germany

69120

+49 6221 56 6200

markus.buechler@med.uni-heidelberg.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2002

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

130

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

Heidelberg

Germany

69120

Sponsor information

Organisation

University of Heidelberg Medical School (Germany)

Sponsor details

Im Neuenheimer Feld 110

Heidelberg

Germany

69120

+49 6221 56 6200

markus.buechler@med.uni-heidelberg.de

Sponsor type

University/education

ROR

<https://ror.org/038t36y30>

Funder(s)

Funder type

University/education

Funder Name

University of Heidelberg Medical School (Germany)

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