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Diverting ileostomy after low anterior resection

Submission date 04/06/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/06/2015	**Overall study status** Completed	
Last Edited 04/08/2016	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
At the moment it's unclear if patients suffering from rectal cancer who undergo surgical treatment (rectal resection) have a potential benefit of a temporary protective stoma (ileostomy)in terms of lower postoperative complications, especially at the colorectal anastomosis. Postoperative complications may lead to significant morbidity and mortality. The aim of our study is to investigate if a protective stoma may prevent severe postoperative complications.

Who can participate?
Adult patients of both sexes (age 19-85 years) suffering from rectal cancer.

What does the study involve?
All patients undergo surgical treatment (rectal resection). Before surgery a randomization of all patients is performed and two groups are created: in one group patients receive a temporary protective stoma (ileostomy) additionally to rectal surgery, in the other group patients are treated without this protective stoma. After the operation and hospital dismissal, all patients are invited to a planned study visit 10 weeks after the operation. Patients who are treated with temporary stoma gets their stoma revised 6 to 8 weeks after the primary operation. In all patients the postoperative course is documented and gets compared in a statistical analysis.

What are the possible benefits and risks of participating?
At the moment it's unclear whether patients who undergo rectal resection without protective stoma have a higher risk of postoperative complication compared to patients treated with temporary stoma. A possible benefit for lower postoperative complications may be the performance of a protective stoma.

Where is he study run from?
Brothers of Mercy Hospital St. Veit/Glan (Austria)

When is the study starting and how long is it expected to run for?
January 2004 to September 2014

Who is funding the study?
Brothers of Mercy Hospital St. Veit/Glan (Austria)

Who is the main contact?
Prof. Jörg Tschmelitsch

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Diverting ileostomy versus no diversion after low anterior resection for rectal cancer: a prospective randomised multicenter trial

Study objectives
To determine whether a protective diverting ileostomy improves short-term outcome in patients with rectal resection and colonic J-pouch reconstruction for low anastomoses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethik-kommission des landes kärnten,14/11/2003, ref: A34/03

Study design
Two-arm randomised open-label multicentre study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Histologically verified and operable rectal cancer

Interventions
Patients were stratified by gender, anastomotic height and preoperative radio-chemotherapy to be operated either by rectal resection and colo-anal/rectal anastomosis with a diverting ileostomy (group A) or rectal resection and colo-anal/rectal anastomosis without protective ileostomy (group B). Patients in both groups with low anastomoses (< 8 cm) were planned to receive a colonic J-pouch reconstruction.

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary efficacy endpoint of the present study was the overall anastomotic leakage rate as defined by one of the following:
1. Radiologic leak: radiologic evidence of a leak in a Gastrografin enema and/or CT scan without clinical signs of anastomotic leakage
2. Clinical leak: radiologic evidence of a leak in a Gastrografin enema and/or CT scan and/or sigmoidoscopy with one or more of the following clinical signs: elevated temperature (> 380C), leucocytosis, peritonitis, putrid or faecal discharge over the drainage or fistulas (recto-vaginal)

Secondary outcome measures
1. Surgical complications related to primary surgery, to the stoma before closure and to secondary surgery for stoma closure
2. Postoperative mortality defined as death on account of any cause during the hospital stay due to the primary operation or stoma closure
3. The length of hospital stay in days for the primary operation and stoma closure

Overall study start date
01/01/2004

Completion date
01/09/2014

Eligibility

Key inclusion criteria
1. Patients aged 19 to 85 years with biopsy-proven and operable rectal cancer
2. Patients with or without preoperative radio-chemotherapy
3. Patients with a distal border of the tumour within 16 cm from the anal verge as demonstrated by rigid rectoscopy
4. Patients with a WHO performance status ≤ 2

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
210

Key exclusion criteria
1. Patients with previous rectal surgery
2. Emergency cases
3. Planned laparoscopic resections
4. Patients suffering from metastatic disease or synchronous colon cancer

Date of first enrolment
01/01/2004

Date of final enrolment
01/09/2014

Locations

Countries of recruitment
Austria

Study participating centre
Department of Surgery, Hospital of the Brothers of Mercy
Sankt Veit an der Glan
Austria
-

Study participating centre
Department of Surgery, Hospital of the Brothers of Mercy
Graz
Austria
-

Study participating centre
Department of Surgery, University of Salzburg
Salzburg
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-

Sponsor information

Organisation
Brothers of Mercy Hospital

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01fxzb657

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Brothers of Mercy Hospital (Austria)

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2016		Yes	No