Trial Description

Title

HAnd-suture versus STApling for Closure of Loop Ileostomy

Trial Acronym

HASTA Trial

URL of the trial

[---]*

Brief Summary in Lay Language

**Patients with history of low anterior resection (LAR) due to rectal cancer and placement of protective loop ileostomy undergoing closure of loop ileostomy.
To investigate differences in frequency of bowel obstruction after stapling versus hand-suture loop ileostomy closure.**

Brief Summary in Scientific Language

Colorectal cancer is the second most common tumor in developed countries, with a lifetime incidence of 5%(1;2). Approximately 30% of these tumors are located in the rectum. Surgery forms the cornerstone in the treatment of rectal cancer, with the low anterior resection (LAR) being the standard procedure(3). A transient protective loop ileostomy should be created in patients undergoing LAR in order to protect the deep rectal anastomosis until definite healing is achieved(4-6). After a period of three months the ileostomy is subsequently closed and intestinal continuity is re-established. Due to the high incidence of rectal cancer, closure of loop ileostomy is a frequently performed procedure in surgical routine. While there are two techniques available for closure of loop ileostomy (the hand-sutured and the stapled anastomosis), valid data are missing which one of these techniques should preferably be used in daily practice.

Organizational Data

- DRKS-ID: **DRKS00000040**
- Date of Registration in DRKS: **2008/10/27**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **S-278/2008 , Ethik-Kommission I der Medizinischen Fakultät Heidelberg**

Secondary IDs

Health condition or Problem studied

- Free text: **Closure of Loop ileostomy after Low anterior resection due to colon carcinoma**
- ICD10: **C18 - Malignant neoplasm of colon**

Interventions/Observational Groups

- Arm 1: **The stapler is brought into the two opened antimesenteric apexes of the intestinal shanks to facilitate side-to-side (functional end-to-end) anastomosis. The apex of the loop and the spout is cross-stapled with a refill of the GIA-stapler followed by overstitching the cross-stapled line with a Polydioxanon equivalent suture (USP 5-0/Ethicon, Norderstedt). The intestine is then put back into the peritoneal cavity. The abdominal wall is closed with interrupted sutures using Polyglactin equivalent sutures (USP 2). The subcutaneous tissue is not sutured and no subcutaneous drainage is used. The skin can be closed by either interrupted monofilament sutures or clips.**
- Arm 2: **After thorough mobilisation the loop ileostomy is resected using two bowel clamps. An end-to-end anastomosis is performed as follows: a two-layer continuous suture using four Polydioxanon equivalent sutures (USP 5-0). The inner layer consists of a transmural suture, the outer layer of a sero-muscular suture. Alternatively interrupted sutures could be performed depending on local standards. The abdominal wall and the skin are closed in the same way as for stapled closure.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **[---]***
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Frequency of bowel obstruction within 30 days after ileostomy closure

Secondary Outcome

Time needed to perform the procedure/Wound infection/Frequency of re-operation due to anastomotic leakage of the ileostomy closure/Time to first tolerance to solid food and first bowel movement, whichever of these occurred last/Length of postoperative hospital stay/30 day and one year mortality after ileostomy closure/Frequency of re-operation and re-hospitalization within one year due to bowel obstruction/Costs of surgical procedure/Quality of life

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Krankenhaus St. Marienwörth, Bad Kreuznach**
- Medical Center **Sanaklinikum, Berlin**
- Medical Center **Schlosspark, Berlin**
- University Medical Center **St. Josef-Hospital, Ruhr-Universität, Bochum**
- Medical Center **St. Josefs-Hospital, Bochum-Linden**
- Medical Center **Caritas-Krankenhaus, Dillingen**
- Medical Center **St. Josefs Hospital, Dortmund**
- University Medical Center **Chirurgische Universitätsklinik, Freiburg im Breisgau**
- Medical Center **Klinikum Freising, Freising**
- University Medical Center **Chirurgische Universitätsklinik, Greifswald**
- Medical Center **Kreiskrankenhaus, Gummersbach**
- University Medical Center **Chirurgische Universitätsklinik, Heidelberg**
- Medical Center **Krankenhaus Salem, Heidelberg**
- Medical Center **Heilig-Geist-Krankenhaus, Köln**
- Medical Center **Krankenhaus Porz am Rhein gGmbH, Köln**
- Medical Center **Klinikum Magdeburg, Magdeburg**
- University Medical Center **Klinikum rechts der Isar der TU, München**
- Medical Center **Klinikum Landkreis Neumarkt, Neumarkt**
- Medical Center **Triamed Kreisklinik Prien am Chiemsee, Prien**
- Medical Center **Klinik am Steinenberg, Reutlingen**
- Medical Center **Klinik für Allgemein-, Gefäß- und Thoraxchirurgie, Rosenheim**
- Medical Center **St. Marien Krankenhaus, Siegen**

- Medical Center **Kliniken Landkreis Sigmaringen, Sigmaringen**
- Medical Center **Krankenhaus Sinsheim, Sinsheim**
- Medical Center **Diakonissenkrankenhaus Speyer-Mannheim, Speyer**
- Medical Center **Marienhospital Stuttgart, Stuttgart**
- Medical Center **Robert-Bosch-Krankenhaus, Stuttgart**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2009/02/13**
- Target Sample Size: **320**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Preoperative
Patients, 18 years or older, scheduled for elective ileostomy closure after Low Anterior Resection (LAR)/Given Inormed Consent

Exclusion criteria

Preoperative:
Pathologic findings in routine preoperative diagnostic tests (e.g anastomotic leakage), which do not allow a safe ileostomy closure./Participation in another intervention trial with interference of intervention and outcome of this study/Expected lack of compliance

Addresses

- **Primary Sponsor**

  Universitätsklinikum Heidelberg - Verwaltung
  Im Neuenheimer Feld 672
  69120 Heidelberg
  Germany

Primary Sponsor

Universitätsklinikum Heidelberg - Verwaltung
Im Neuenheimer Feld 672
69120 Heidelberg
Germany

Telephone: **+49 6221 56 0**
Fax: **[---]***
E-mail: **[---]***
URL: **http://www.klinikum.uni-heidelberg.de/Startseite.2.0.html**

■ **Contact for Scientific Queries**

Chirurgische Klinik der Universität Heidelberg
Ms. Inga Rossion
Im Neuenheimer Feld 110
69120 Heidelberg
Germany

Telephone: **+49 6221 56 6984**
Fax: **+49 6221 56 6988**
E-mail: **Inga.Rossion at med.uni-heidelberg.de**
URL: **http://www.sdgc.de**

■ **Contact for Public Queries**

SDGC Heidelberg
Chirurgische Klinik der Universität Heidelberg
Ms. Inga Rossion
Im Neuenheimer Feld 110
69120 Heidelberg
Germany

Telephone: **+49 6221 56 6986**
Fax: **+49 6221 56 6988**
E-mail: **sdgc at med.uni-heidelberg.de**
URL: **http://www.sdgc.de**

Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

Universitätsklinikum Heidelberg - Verwaltung
Im Neuenheimer Feld 110
69120 Heidelberg
Germany

Telephone: **+49 6221 56 0**
Fax: **[---]***

Institutional budget, no external funding (budget of sponsor/PI)

Universitätsklinikum Heidelberg - Verwaltung
Im Neuenheimer Feld 110
69120 Heidelberg
Germany

Telephone: **+49 6221 56 0**
Fax: **[---]***
E-mail: **[---]***
URL: **http://www.klinikum.uni-heidelberg.de/Startseite.2.0.html**

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

Johnson & Johnson MEDICAL
Hummelsbütteler Steindamm 71
22851 Norderstedt
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **2011/10/27**

Trial Publications, Results and other documents

- Paper **Veröffentlichung Studienprotokoll**
- Trial results **Löffler T, Rossion I, Bruckner T, Diener MK, Weitz J et al; HASTA Trial Group: HAnd Suture versus STApling for Closure of Loop Ileostomy (HASTA Trial): results of a multicenter randomized trial (DRKS00000040). Ann Surg. 2012 Nov;256(5):828-35; discussion 835-6. doi: 10.1097/SLA.0b013e318272df97**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*