Trial Description

Title

Postoperative negative pressure incision therapy following open colorectal surgery: a randomized-controlled trial

Trial Acronym

Poniy

URL of the trial

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Brief Summary in Lay Language

More than 20% of patients develop surgical site infections following colorectal surgery, which cause substantial morbidity, prolongation of hospital stay, costs and even mortality. A novel negative pressure incision therapy device, which is applied for 5-7 days postoperative, was developed to reduce surgical site infections by continuous removal of wound secretion from the incisional wound. However, the device has not yet been tested in a high-quality trial and its effectiveness is therefore unclear. The Poniy trial will investigate, whether this negative pressure incision therapy device reduces wound infections in comparison to standard wound coverage in patients undergoing open elective colorectal surgery.

Brief Summary in Scientific Language

The aim of the trial is to investigate whether negative pressure incisional therapy for 5-7 days postoperative significantly reduces postoperative surgical site infections in comparison to standard wound dressings following open elective abdominal surgery.

Organizational Data

- DRKS-ID: **DRKS00006199**
- Date of Registration in DRKS: **2014/08/20**
- 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.: **155/14 , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- Free text: **open colorectal surgery**

Interventions/Observational Groups

- Arm 1: **Postoperative wound coverage with negative pressure incisional therapy device (PrevenaTM Incision Management System) for 5-7 days postoperative.**
- Arm 2: **Postoperative wound coverage with standard dressings for 5-7 days postoperative.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist, assessor, data analyst**
- Control: **Active control (effective treament of control group)**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Rate of surgical site infections according to the definition of the Centers for Disease Control and Prevention within 30 days postoperative.

Secondary Outcome

1.) Length of hospital stay
2.) Rate of reoperations
3.) Rate of antibiotic theray
4.) Duration of postoperative negative pressure incision therapy (intervention arm only)
5.) Wound pain assessed with visual analogue scale
6.) Rate of wound complications other than wound infections
7.) Rate of serious adverse events

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **CHIR-Net, München**
- Medical Center **CHIR-Net, Bamberg**
- Medical Center **CHIR-Net, Ilmtalklinik Pfaffenhofen**
- Medical Center **CHIR-Net, RoMed Klinik Prien am Chiemsee**
- Medical Center **CHIR-Net, Maria-Theresia-Klinik München**
- Medical Center **CHIR-Net, Klinikum Bogenhausen München**
- Medical Center **CHIR-Net, Klinikum St. Elisabeth Straubing GmbH**
- Medical Center **CHIR-Net, Rotkreuzklinikum München**
- Medical Center **CHIR-Net, Kreiskliniken Altötting-Burghausen**
- Medical Center **CHIR-Net, Kreisklinik Ebersberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/01**
- Target Sample Size: **340**
- 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

1.) Planned elective open colorectal surgery via median or transverse laparotomy
2.) Age 18 years or older
3.) Ability to understand the nature and extend of the trial and to sign the written informed consent.

Exclusion criteria

1.) Pregnancy or breast-feeding
2.) Median or transverse laparotomy within the last 60 days prior to inclusion into the study.
3.) Planned relaparotomy within 30 days
4.) Laparoscopic or laparoscopic assissted surgery
5.) Patients on preoperative antibiotic treatment

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** 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.*