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Reducing the surgical site infection rate after loop colostomy reversal by application of vacuum assisted delayed wound closure

Submission date
30/10/2011

Recruitment status
Stopped

Registration date
20/01/2012

Overall study status
Stopped

Last Edited
30/06/2017

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A loop colostomy is a surgical procedure where a loop of the large intestine (colon) is pulled out through a hole in the abdomen, before being opened up and stitched to the skin to form an opening called a stoma. Loop colostomies tend to be temporary and require a further operation at a later date to reverse the procedure. The standard procedure after stoma closure is primary wound closure. The aim of this study is to compare the standard procedure with an alternative approach of applying a vacuum dressing into the wound and delayed wound closure after 48 hours.

Who can participate?
Participants aged 18 or over undergoing loop colostomy reversal

What does the study involve?
Participants are randomly allocated to undergo either the standard procedure for wound closure or the alternative approach of applying a vacuum dressing into the wound and delayed wound closure after 48 hours. The rate of surgical site infections is compared between the two groups.

What are the possible benefits and risks of participating?
The vacuum-assisted closure should reduce the rate of surgical site infections.

Where is the study run from?
Armed Forces Hospital (Germany)

When is the study starting and how long is it expected to run for?
December 2011 to December 2014.

Who is funding the study?
German Army (Germany)

Who is the main contact?
Dr Stefan Benesch
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Study website
http://www.stomavac.darmzentrum-bwkulm.de

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
Reducing the surgical site infection rate after loop coloSTOMy reversal by Application of Vacuum Assisted delayed wound Closure: a randomized controlled trial

Acronym
STOMAVAC

Study objectives

To investigate the conditioning effect of VAC to colostomy wounds prior to delayed primary closure. A reduction of the substantial high rate of superficial and deep surgical site infection rates of 30% is expected.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Single-center stratified parallel-group randomized controlled clinical 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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Surgical site infection rate, negative-pressure wound therapy

Interventions
After hospital admission, an x-ray series of both limbs of the stoma is taken with radiopaque material. Where required, further cardiopulmonary diagnostic measures are done the day before surgery.
The colon cleansing is done by drinking 90 ml (two bottles) of a phospho-soda solution together with at least of two litres of water. At the morning of the surgery day a colonoscopy of both the afferent and efferent limb of the large bowel is to be done. To enhance the adherence to the protocol and to avoid clustering effects all operations will either be performed or assisted by one of two surgeons who are colorectal surgeons and have the same surgical expertise.
Antibiotic prophylaxis is given one hour preoperatively (tazobactam + piperacillin/metronidazol).
First, a circular incision is done directly along the stoma edges. After that, the stoma is mobilized until the fascia of the externus muscle is achieved. Then, using scissors, the stoma will be mobilized out of the abdominal wall. Approx. 3 cm oral and aboral the stoma opening the colon is tunneled and cut with a linear stapler. This is followed by a centrally directed V-shaped incision and dissection of the mesocolon. The blood vessels are each supplied with a ligature. Epiploic appendices located opposite to the mesocolon are removed over a distance of 6cm at both ends. The staple lines are now opened on the corner and the two limbs are laid side by side in parallel, so that now a functional end-to-end stapled anastomosis can be created. Finally, the

mesocolonic slit is closed with a continuous suture. Then the anastomosis is shifted back into the abdominal cavity. An intraperitoneal drainage is not inserted. The peritoneum is closed with continuous stitches. Now, a swab is taken from the subcutaneous tissue for microbiological examination. Then the abdominal wall and subcutaneous tissue is rinsed with Octenisept® solution and after that rinsed with saline solution. This is followed by a glove change. The fasicas are the closured with continous stitches using a PDS-loop.

The further procedures depend on the randomization that was performed on the day before surgery:

Intervention group
A VAC sponge is prepared and fitted into the subcutaneous wound. The wound edges are cleaned, then the wound is sealed with a continuous suction of 125 mmHg for 48 hours. 48 hours after surgery the VAC-system is removed, a swab is taken and without flushing it the subcutaneous tissue is sutured. This is followed by an infiltration of the wound edges with Naropin® and skin closure using interrupted stitches. At this time any adverse effects of VAC therapy are documented.

Control group
The subcutaneous tissue is closed with sutures. This is followed by an infiltration of the wound edges with Naropin and skin closure using interrupted stitches. The postoperative management regarding mobilization and return to solid food follows the fast track principle in both groups. Starting with the second postoperative day after definitive wound closure daily dressing changes are done. The wound status is assessed daily at the ward by the respective senior attending on the basis of the Centre for Disease Control (CDC) criteria for defining a superficial or deep wound infection. After taking swabs the wound is cleaned, disinfected and covered with a plaster. For documentation purposes, additionally a macro photo of the wound is made. With unremarkable course, returned peristalsis and healed anastomosis in the control group the patients can be discharged at 8th postoperative day and in the intervention group at 6th postoperative day after definitive wound closure. So for both groups the same length of minimum treatment time is guaranteed. At the day of discharge a wound swab is taken. Additional discharge criteria are normal wound conditions, completion of mobilization and ingestion of food and declined inflammation parameters. If a superficial wound infection occurs without affection of the subcutaneous tissue the stitches of the skin are removed and a swab is taken for microbiological examination. This is followed by a conservative regimen. Once the out-patient care is guaranteed by a professional nurse wound, the patient may be discharged from inpatient treatment. If the subcutaneous tissue is also affected, a surgical treatment like that in deep SSI follows except re-opening of the fascia and muscle layer. If a deep wound infection is present, the wound in the operating room is fully opened. A swab is taken, then the wound is debrided, flushed and vacuum sealed after closure of the peritoneum. This is followed by several seal changes until the wound appears clean and the last swab is sterile. Then either a secondary wound closure will follow or the wound is left open for secondary wound closure. Afterwards the patient can be discharged. On suspicion of an anastomotic leak a CT scan of the abdomen is performed with transrectal radiopaque material filling. If the suspicion is confirmed, a revision surgery is performed with resection of the anastomosis. Depending on the intraabdominal situation a new anastomosis and a protective loop ileostoma or a double-barrel stoma is created. With discharging the patients from hospitalization they receive an appointment for outpatient follow-up at the 10th-12th postoperative day. At this time all stitches are removed and a swab is taken. A further follow-up examination follows at day 30 after first surgery. The quality of life-score is evaluated using SF-36 at the day of admission and day 30.

Intervention Type

Procedure/Surgery

Primary outcome measure
The rate of superficial and deep surgical site infections (SSIs) after ostomy takedown (in a period of 30 days postoperative after colostomy reversal) based on the CDC criteria for definition of a wound infection

Secondary outcome measures
The influence of the particular treatment on the quality of life (assessed with SF-36), and to evaluate factors, which might influence the rate of SSIs

Overall study start date
01/12/2011

Completion date
01/12/2014

Eligibility

Key inclusion criteria
1. Eligible participants are all adults aged 18 or over
2. Loop colostomy to be reversed
3. Signed informed consent for participating in the study

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Patients with inflammatory bowel diseases
2. Persons who received systemic steroids within the last year

Date of first enrolment
01/12/2011

Date of final enrolment
01/12/2014

Locations

Countries of recruitment
Germany

Study participating centre
Armed Forces Hospital
Ulm
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89081

Sponsor information

Organisation
Armed Forces Hospital (Germany)

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Sponsor type
Government

ROR
https://ror.org/05qz2jt34

Funder(s)

Funder type
Government

Funder Name
German Army (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