

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

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## 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

**Contact name**

Dr Stefan Benesch

**Contact details**

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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 fascias are closed with continuous 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 outpatient 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

Germany

89081

## **Sponsor information**

### **Organisation**

Armed Forces Hospital (Germany)

### **Sponsor details**

Oberer Eselsberg 40

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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