ClOsed Negative-pressure wound Therapy After ColorecTal Surgery

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Interventional

Summary

ID

NL-OMON55599

Source
ToetsingOnline

Brief title
CONTACT

Condition

- Ancillary infectious topics
- Skin and subcutaneous tissue disorders NEC

Synonym
surigical site infection, wound infection

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Smith en Nephew,Smith&Nephew, Inc

Intervention

Keyword: Colorectal, negative-pressure, therapy, wound

Outcome measures

Primary outcome

The primary endpoint is the incidence of incisional SSI within 30 days of surgery. In accordance with Centre for Disease Control and Prevention (CDC) and National Healthcare Safety Network (NHSN) SSI is defined as (24, 25) as:

Superficial incisional SSI

Infection occurs within 30 days after surgery and infection involves only skin or subcutaneous tissue of the incision and at least one of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Deep incisional SSI

Infection occurs within 30 days after surgery if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation and Infection involves deep soft tissues (eg fascial and muscle layers) of the incision and at least 1 of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38.0°C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Secondary outcome

• QoL

QoL will be assessed using the SF36 and EQ-5D-5L questionnaire, which will be conducted at admission, day 30 and day 365 postoperatively.

• Postoperative complications

All postoperative complications will be recorded in the Case Reporting Form (CRF) including date of occurrence, diagnosis procedure and treatment.

• Cost

Cost will be considered the analysis of the device*s cost versus the effectiveness of its usage by decreasing the incidence of the SSI. Reduction in health related problems as a consequence will economically be analysed at day 30 and day 365 postoperatively using the SF-HLQ questionnaire.

• Cosmesis

Cosmesis will be assessed 365 days after the surgery by complying the POSAS questionnaire from the patient and the observer(26).

Study description

Background summary

Surgical site infection (SSI) following abdominal surgery is considered one of the most significant and frequent complications resulting in mortality, morbidity, and costs(1-3). In previous literature it has been indicated that SSI significantly increases length of hospital stay, morbidity and induces psychological effects.
Through time, surgeons have explored different interventions to decrease the SSI rate, beyond pre-operative antibiotic prophylaxis and aseptic techniques. Negative pressure wound therapy (NPWT) was reported for the first time in 1997, as a novel technique, by Argenta et al. which brought a revolution in treating chronic and other difficult-to-manage wounds(4). Usage of NPWT is now a widely accepted therapy for secondarily healing wounds and nowadays the application of NPWT to surgical incision healing by primary intention is a subject undergoing intense study in different disciplines(5-7). Beside a decrease in SSI rate, decreases in serous exudative rates and good healing of incisions post-operatively have also been reported(5, 6). Blackham et al. performed a retrospective analysis of 191 operations for colorectal, pancreatic, or peritoneal surface malignancies, and found a decrease of SSI in the group using NPWT versus the control group (6.0% vs 27.4%, P = .001) (8). Bonds et al. showed the same results in a retrospective cohort study, where a significant difference was reported in SSI incidence between NPWT group and the ones undergoing standard closure (12.5% versus 29.3%)(9).
More than two decades after its introduction, laparoscopic approach has become the standard of care for colorectal surgery(10). The feasibility and advantages of laparoscopic approach have been well documented(11). Despite prophylactic

and sterility measures implemented pre- per- and post-intervention, (preoperative antibiotic use and aseptic operative technique) SSI rates following laparoscopic colorectal surgery remain high and vary from 4% to 16.7%(12-18). Given the significant patient morbidity associated with this complication, this field represent a significant research gap with priority need for future studies.

Study objective

The aim of our study is to investigate whether NPWT in closed incisional wounds decreases the rate of SSI, in patients undergoing laparoscopic or open colorectal surgery with a minimal incisional length of 30mm.

Primary Objective: The primary objective is to determine the reduction of SSI by NPWT for closed incisional wounds.
Secondary Objectives: The secondary objective is to evaluate the QoL, postoperative complications, cost and cosmesis.

Study design

The CONTACT trial is a randomized controlled trial (RCT), designed as an European, multicenter, open-label, superiority trial, in which the efficacy and effectiveness of the NPWT in closed wounds will be assessed in preventing SSI. The study will have a 1-year follow-up where the development of SSI, QoL, post-operative complications, cosmesis and cost will be evaluated.

Intervention

NPWT especially designed for closed wounds under the brand name Pico* is the investigational product in this study. Its features include a single-patient use continuous vacuum system set to 80 mm Hg, connected to the sponge dressing, placed under sterile conditions in the operating room and would be maintained 7 consecutive days after the surgery.

The control group is going to receive SSD, which is the standard practice for incisional wounds after colorectal surgery covering laparoscopy or laparotomy incision. The SSD will be changed according to the standard protocol and routine of care for each site.

Study burden and risks

Based on previous studies and clinical experience, a relative reduction of the SSI rate by 50% is expected in the patients using the NPWT device.
If the usage of the NPWT device leads to unexpected complications that have large influence on the patient*s well being early termination should be taken into consideration. However, previous studies in other disciplines showed that

the usage of the device is safe and there is no major complication related to its usage(28-30). NPWT devices are widely used products in surgery, so we do not expect any problems of such an impact. In case the study is ended prematurely, the coordinating PI will notify the accredited METC and the competent authority within 15 days, including the reasons for the premature termination.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3000CA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3000CA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients >= 18 years old, undergoing laparoscopic or open colorectal surgery and have the ability to understand and willing to sign the written informed consent.

Exclusion criteria

- pregnancy
- patients with known allergies to the adhesive materials that would be used
- perineal wounds
- perioperative HIPEC treatment
- purse-string suture

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2021
Enrollment:	900
Type:	Actual

Medical products/devices used

Generic name:	PICO
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	17-12-2019
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam

	(Rotterdam)
Approved WMO Date:	21-01-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 23267
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL68929.078.19
OMON	NL-OMON23267