ClOsed incision Negative pressure wound Therapy After ColorecTal Surgery: A randomized controlled trial

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23267

Source
NTR

Brief title
CONTACT-Trial

Health condition

Closed incision surgical site infection after colorectal surgery.

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Smith & Nephew

Intervention

Outcome measures

Primary outcome

Primary outcome is the occurrence of a surgical site infection in respectively the control and study groups at any time up to 30 days, with margin of 5 days, after surgery.

Secondary outcome

Secondarily quality of life as assessed through the VAS Pain and EQ-5D-5L questionnaires, cost, number of complications (overall and per type of complication) and cosmetic satisfaction will also be assessed.

Study description

Background summary

Rationale: Surgical site infection (SSI) following abdominal surgery is considered one of the most significant and frequent complications resulting in mortality, morbidity, and costs.

Objective: Reduction of surgical site infection. Secondary objectives include assessment of quality of life (QoL), post-operative complications, wound cosmesis and cost-effectiveness of using negative pressure wound therapy (NPWT) device.

Study design: European Multicenter, open-label, randomized controlled trial.

Study population: Patients aged 18 years and older, undergoing laparoscopic or open colorectal surgery
Intervention: Patients will be asked for informed consent, and will receive NPWT dressing in the study group, and standard surgical dressing (SSD) in the control group.

Main study parameters/endpoints: The primary study endpoint is clinically assessed surgical site infection.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The extent of the burden and risks associated participation could be considered as small. The invasive procedure performed on behalf of the CONTACT trial is usage of NPWT dressing performed at the operating theatre under sterile conditions. Previous studies in other disciplines have shown superiority of NPWT in preventing surgical site infections. No major risk of the device have been reported since it is used in other disciplines, however patients might experience discomfort, hematomas and allergic reaction to the materials composing the device.

Study objective

Negative pressure wound therapy reduces surgical site infections after colorectal surgery.

Study design

Occurence of surgical site infections up to 30 days and quality of life, cosmetic satisfaction of the woundhealing and (in)direct costs of the treatment one year after surgery.

Intervention

Application of negative pressure wound therapy (PICO 7 device) on closed surgical incisional wounds.

Contacts

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Eligibility criteria

Inclusion criteria

Patients ≥ 18 years old
Patients undergoing laparoscopic or open colorectal surgery
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)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	11-02-2021
Enrollment:	1000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-02-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 55599
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9287
CCMO	NL68929.078.19
OMON	NL-OMON55599

Study results