

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

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23267

Bron

NTR

Verkorte titel

CONTACT-Trial

Aandoening

Closed incision surgical site infection after colorectal surgery.

Ondersteuning

Primaire sponsor: Erasmus MC

Overige ondersteuning: Smith & Nephew

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Occurrence 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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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010-7043683

Wetenschappelijk

Erasmus MC
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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients $\geq$ 18 years old
Patients undergoing laparoscopic or open colorectal surgery
The ability to understand and willing to sign the written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Pregnancy
Patients with known allergies to the adhesive materials that would be used
Perineal wounds
Perioperative HIPEC treatment
Purse-string suture

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	11-02-2021
Aantal proefpersonen:	1000
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies	
Datum:	11-02-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 55599
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten