The PRESSURE Trial

No registrations found.

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

Summary

ID

NL-OMON22141

Source
NTR

Brief title
PRESSURE

Health condition

Incisional hernia
Ventral hernia
Surgical site occurrences
Postoperative wound complications
Surgical site infection
Contaminated
Contamination

Littekenbreuk
Hernia
Postoperatieve wondcomplicaties
Postoperatieve wondinfectie
Gecontamineerd
Contaminatie

Sponsors and support

Primary sponsor: Academic Medical Center, Amsterdam
Source(s) of monetary or material Support: Investigator-initiated. Material support only.

Intervention

Outcome measures

Primary outcome

The percentage of patients with at least one clinically relevant surgical site occurrence (SSO) within 30 days after surgery.

Clinically relevant surgical site occurrences are defined as:

Surgical site infection

Wound cellulitis

Wound dehiscence

Enterocutaneous fistula

Seroma

Hematoma

Skin ischemia/necrosis

*A SSO is considered clinically relevant when the attending physician considers the SSO of being of such severity that it needs further action for purposes of clinical diagnosis (other than clinical examination) or treatment, such as ultrasound/CT, antibiotics, drainage or surgery. The term “attending physician” is interpreted to mean the surgeon(s), infectious disease specialist, other physician on the case, emergency physician or physician’s designee (nurse practitioner or physician’s assistant).

Secondary outcome

-QoL (EQ-5D-5L)

-Recurrence 1 year after surgery

-The individual components of primary outcome SSO at <30, <90, <1 year after surgery

-Peri-incisional SSO

-The percentage of patients with signs of SSO on photographs by blinded outcome assessment

-Frequency and type of procedures related to SSO

-Hospital stay after surgery in days

-Earlier removal of iNPWT because of SSO

-Emergency department visits after discharge

-Readmission within 30 days, 90 days and within a year for any complication

-30-day, 90-day, in-hospital and 1-year mortality

-Non-primary outcome complications (e.g. ileus, pneumonia)

-Cost-effectiveness (The Netherlands only)

Study description

Background summary

SUMMARY

Rationale & Objective:

With an incidence of up to 46% in contaminated abdominal wall reconstruction, surgical site occurrences (SSO) are an overly frequent problem in leading to significant morbidity and mortality. Evidence suggests incisional negative pressure wound therapy (iNPWT) reduces SSO in clean surgery. However, there is a paucity of RCTs describing usage of iNPWT in contaminated surgery. Therefore, we propose conducting this RCT with the hypothesis that iNPWT decreases the number of patients that develop SSO in contaminated abdominal wall reconstruction.

Study design:

An investigator-initiated, multinational, multicenter, pragmatic, randomized controlled trial with parallel group superiority design in our collaborative international network, randomizing 388 patients with a 1:1 ratio.

Study population:

In order to participate in this trial, a subject must meet the following criteria:

• ≥18 years

• Scheduled for elective, open abdominal wall reconstruction

• Pre-operative CT available performed within 12 month after last abdominal intervention

And one of the following:

• A stoma or enterocutaneous fistula and a defect of >6 cm* in size on CT

• Violation of the gastrointestinal tract** and defect of >6 cm in size on CT

• Infected mesh (any size)

• Septic dehiscence (any size)

*In case of parastomal hernia and the patient is candidate for ostomy takedown or relocation, the resulting defect in the abdominal wall should be taken for this measure

Intervention:

In this trial, commercially available incisional negative pressure wound therapy will be compared with conventional wound care (defined as a simple, sterile, gauze based dressing as routinely used at the participating hospital site).

Main study endpoint:

The primary outcome is the number of patients with at least one surgical site occurrence (surgical site infection, wound dehiscence, enterocutaneous fistula, seroma, hematoma, skin or wound ischemia/necrosis) 30 days after surgery, with extended follow-up at 90 days and 1 year after surgery. The amount of distinct surgical site occurrence components (e.g. dehiscence) will be registered as secondary outcome as well. Other important secondary outcomes are QoL and hernia recurrence.

Study objective

Incisional negative pressure wound therapy reduces the amount of patients with clinically relevant surgical site occurrences within 30 days after contaminated abdominal wall reconstruction.

Study design

30 days, 90 days, and one year after surgery

Intervention

Incisional negative pressure wound therapy

Contacts

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Eligibility criteria

Inclusion criteria

• ≥18 years

• Informed consent

• Scheduled for elective, open abdominal wall reconstruction*

• Pre-operative CT available performed within 12 months after the last abdominal intervention

And one of the following:

• A stoma or enterocutaneous fistula and an abdominal wall defect of >6 cm** on CT

• Violation of the gastrointestinal tract and an abdominal wall defect of >6 cm on CT

• Infected mesh (any size)

• Septic dehiscence (any size)

Exclusion criteria

• Patients <18

• Parastomal hernias in which the stoma is not being relocated or taken down and the parastomal hernia is the only defect planned for reconstruction*

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):	01-04-2018
Enrollment:	388
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 06-09-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56300
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6488
NTR-old	NTR6675
CCMO	NL60054.018.16
OMON	NL-OMON56300

Study results