The PRESSURE Trial

Gepubliceerd: 06-09-2017 Laatst bijgewerkt: 19-03-2025

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

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

Samenvatting

ID

NL-OMON22141

Bron
Nationaal Trial Register

Verkorte titel
PRESSURE

Aandoening

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

Littekenbreuk
Hernia
Postoperatieve wondcomplicaties
Postoperatieve wondinfectie
Gecontamineerd
Contaminatie

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam

Overige ondersteuning: Investigator-initiated. Material support only.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

30 days, 90 days, and one year after surgery

Onderzoeksproduct en/of interventie

Incisional negative pressure wound therapy

Contactpersonen

Publiek

AMC
A.S. Timmer
Department of Surgery, Academic Medical Center

G4-129 PB 22660

Amsterdam 1100 DD
The Netherlands
+31 (0)20 566 2661

Wetenschappelijk

AMC
A.S. Timmer
Department of Surgery, Academic Medical Center

G4-129 PB 22660

Amsterdam 1100 DD
The Netherlands

+31 (0)20 566 2661

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• ≥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)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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*

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2018
Aantal proefpersonen:	388
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:	06-09-2017
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56300
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten