The effect of postoperative negative pressure wound therapy on the incidence of wound dehiscence in high risk patients

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28116

Source
NTR

Brief title
DEPRES

Health condition

Humans, post operative care, elective abdominale surgery, elective othopedic surgery, elective vascular surgery, elective plastic surgery (Deep Internal Epigastric Perforator flap (DIEP-flap) and Profunda Artery Perforator flap (PAP-flap), wound dehiscence; wound rupture, surgical site infection, negative pressure wound therapy, wound management, standard wound dressing, postoperative bandage

Mensen, postoperatieve zorg, electieve abdominale operatie, electieve orthopedische operatie, electieve vaatoperatie, electieve plastisch chirurgische operatie (Deep Internal Epigastric Perforator flap (DIEP-flap) en Profunda Artery Perforator flap (PAP-flap), wonddehiscentie, wondruptuur, postoperatieve wondinfectie, negatieve druktherapie, wondverzorging, (standaard), postoperatief verband

Sponsors and support

Primary sponsor: Radboud University Medical Center
Postbus 9101, 6500 HB Nijmegen 10 (NL)
Geert Grooteplein-Zuid

Department of Plastic Surgery
Source(s) of monetary or material Support: Ministery of OC&W (research foundation of universities)

Intervention

Outcome measures

Primary outcome

wound dehiscence

measured by visible wound dehiscence (wound dehiscence was measured in centimeters)

Secondary outcome

1 surgical site infection measured when clinical signs of surgical site infection are present and by measuring the temperature of the body

2 pain is measured by asking for the patiënt's pain experience by using the Numeric Rating Scale of Pain (NRS)

3 allergy on the wound dressing measured by signs of allergy like: erythema, itch, edema, hematoma

Study description

Background summary

Wound dehiscence is a serious postoperative complication with high morbidity and high mortality (up to 50%) and contributes to delays in the recovery process and to prolonged hospital stays.

Several case series show the positive effect of Prevena™ Incision Management System in the prevention of wound dehiscence, but good quality scientific research on this intervention is lacking. This randomized controlled study on this intervention (Prevena™ Incision Management System) is started in February 2015 in the Netherlands at the Radboud University Medical Center of Nijmegen and finished in 2016.

The aim of this study is to answer the question whether postoperative treatment with a wound dressing with negative pressure (Prevena™ Incision Management System) decreases the incidence of wound dehiscence compared to a wound dressing without negative pressure (standard wound dressing/care as usual) in high-risk patients undergoing an plastic surgical procedure.

Study objective

Wound dehiscence is the rupturing or splitting apart of the margins of a clean closed incision, which generally appears in the first week after surgery.

The aim of this study is to answer the question whether postoperative treatment with a wound dressing with negative pressure (Prevena™ Incision Management System) decreases the incidence of wound dehiscence compared to a wound dressing without negative pressure (standard wound dressing/ care as usual) in high-risk patients undergoing an elective plastic surgical breast reconstruction.

Study design

T-1 = inclusion/exclusioncriteria, informed consent form, patiënts characteristics

T0 = surgery data

T1- T7 (1 week)= registration of body temperature, blood pressure, heart frequency, blood oxygen level, pain (NRS-score), allergy on the wound dressing, wound dehiscence

T8 = (4 weeks after surgery)= registration of pain (NRS-score), allergy on the wound dressing, wound dehiscence

Intervention

In the experimental group Prevena™ Incision Management System is applicated in clean closed surgical incisions.

In the controlgroup a simple cotton wound dressing is applicated in clean closed surgical incisions. (care as usual, according to the CDC- Guidlines for Surgical Site Infection, 2014)

Contacts

Public
Radboud University Medical Center

Emmy Muller-Sloof
Postbus 9101

Nijmegen 6500 HB
The Netherlands
M 00 31 (0) 611090325
Scientific
Radboud University Medical Center

Emmy Muller-Sloof
Postbus 9101

Nijmegen 6500 HB
The Netherlands
M 00 31 (0) 611090325

Eligibility criteria

Inclusion criteria

* male and female persons

* age 18 years or older

* signed informed consent form

* able to understand the Dutch language

* able to understand procedures and instructions

* patients undergoing one of the following elective sugical procedures:

o plastic surgery through a transverse abdominal (DIEP flap) or sublgluteal (PAP flap) incision

* patients with at least one risk factor for wound dehiscence like:

o chronic obstructive pulmonary disease

o diabetes mellitus

o peripheral artery disease

o body mass index >30

o smoking

o radiotherapy in history

o earlier surgery in the same area

o traction on the suture line

Exclusion criteria

- incompetence

- open fracture

- fistula(s) in the area of the incision

- simultaneous participation in another scientific study

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-02-2015
Enrollment:	51
Type:	Actual

Ethics review

Positive opinion

Date:	25-04-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5512
NTR-old	NTR5808
Other	NL51649.091.14 (2014-1443) : 51649 (ABR-nummer)

Study results

Summary results
non