

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

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

Samenvatting

ID

NL-OMON28116

Bron

NTR

Verkorte titel

DEPRES

Aandoening

Humans, post operative care, elective abdominale surgery, elective orthopedic 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

Ondersteuning

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

Department of Plastic Surgery

Overige ondersteuning: Ministry of OC&W (research foundation of universities)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

wound dehiscence

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

T-1 = inclusion/exclusion criteria, informed consent form, patients 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

Onderzoeksproduct en/of interventie

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

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- * 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 surgical procedures:
 - o plastic surgery through a transverse abdominal (DIEP flap) or subgluteal (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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- incompetence
- open fracture
- fistula(s) in the area of the incision
- simultaneous participation in another scientific study

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	12-02-2015
Aantal proefpersonen:	51
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum: 25-04-2016

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

non