Effect of postoperative negative pressure wound therapy (Prevena TM) in clean closed surgical incisions on the incidence of wound dehiscence in low and high risk patients: a rondomized controlled pilotstudy.

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The aim of this study is to compare the effect of a postoperativenegative pressure dressing (Prevena (TM) IMS) with a standardwound dressing (care as usual) in clean closed surgical wounds on the prevention of wounddehiscence in low riks and high...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Procedural related injuries and complications NEC
Study type	Interventional

Summary

ID

NL-OMON42830

Source
ToetsingOnline

Brief title
DEhiscence PRevention Study II (DEPRES II)

Condition

- Procedural related injuries and complications NEC
- Skin and subcutaneous tissue disorders NEC
- Therapeutic procedures and supportive care NEC

Synonym
Wound dehiscence; wound rupture

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Acelity KCI Kinetic Concepts leverancier Prevena TM

Intervention

Keyword: Negative Pressure Therapy, Surgical wounds, Wound dehiscence, Wound healing

Outcome measures

Primary outcome

wound dehiscence

woundinfection (Surgucal Site Infection)

Secondary outcome

pain (on wound dressing)

skin tension pre operative and postoperative

Study description

Background summary

Wound dehiscence is the rupturing or splitting apart of the edges of a wound closure. Wound dehiscence is a severe
postoperative complication with a high morbidity and mortality.
Prevena (TM) IMS is a new aid (negative pressure dressing) in preventing this complication. Case series are promesing.
In DEPRES I (2015-2016) the effect of Prevena TM was statistically significant but mostly based on mild wound dehiscence , grade 1 and 2, (which can be treated by care as usual like standard wound dehiscence) because mainly patients without risk factors were included. In spite of former studies, good quality scientific research on this intervention is lacking.

Study objective

The aim of this study is to compare the effect of a postoperativenegative pressure dressing (Prevena (TM) IMS) with a standard wound dressing (care as usual) in clean closed surgical wounds on the prevention of wounddehiscence in low riks and high patients for wound dehiscence undergoing an elective plastic surgical surgery

Study design

Open randomized controlled pilotstudy that will be performed in the Radboud University Medical Center Nijmegen (plastic surgery) with n=80 patients. Low risk patients will be allocated to either the interventiongroup (n=20) or the control group (n=20) and high risk patients the interventiongroups (n=20) or the controlgroup (n=20).

Intervention

In the experimental/intervention group Prevena* Incision Management System is applicated in clean closed surgical incisions (7 days)
In the controlgroup a simple wounddressing steristrips (care as usual) is applicated in clean closed surgical incisions (2 days)

Study burden and risks

allergy to the wounddressing
If necessary about 20 minutes extra time (exclusive travel time) for visiting patient clinic

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein Zuid 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* age 18 years or older
* signed informed consent form
* able to understand the Dutch language
* able to understand procedures and instructions
* no risk factor for wound dehiscence
* OR
* at least one risk factor for wound dehiscence:
- Diabetes Mellitus (DM)
- Body mass index >= 30
- active smoker (active and smoker in history)
- radiotherapy (Active and in history)
- COPD chronic obstructive pulmonary disease;AND patients undergoing one of the following elective sugical procedures:
o plastic surgery breastrecontruction through a abdominal transverse incision (DIEP flap or a typelike esthetical breastrecontruction)
o pressure ulcer surgery: for example rotation lap (skin and/or muscle fascia)
o VY-plasty technique
o TFL-flap (tensor fascia lata)

Exclusion criteria

incompetence
fistulas in the area of the incision

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2017
Enrollment:	80
Type:	Actual

Medical products/devices used

Generic name:	Prevena Incision Management System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	14-06-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-01-2018
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
CCMO	NL60146.091.16