Effect of a negative pressure dressing (Prevena TM) on the prevention of wound dehiscence in clean closed surgical incisions: a rondomized controlled trial.

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The aim of this study is to compare the effectiveness of a negative pressure dressing (Prevena (TM) IMS) with a standard wound dressing (care as usual) in clean closed surgical wounds on the prevention of wounddehiscence in patients, undergoing an…

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

Summary

ID

NL-OMON42308

Source
ToetsingOnline

Brief title
Dehiscence Prevention Study (DEPRES)

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: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

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

Outcome measures

Primary outcome

wounddehiscence

Secondary outcome

surgical site infection

pain

allergy for the wounddressing

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) to prevent this complication. Case series are promesing. However, good quality scientific research on this intervention is lacking.

Study objective

The aim of this study is to compare the effectiveness of a negative pressure dressing (Prevena (TM) IMS) with a standard wound dressing (care as usual) in clean closed surgical wounds on the prevention of wounddehiscence in patients, undergoing an elective general, vascular, orthopedic or plastic surgical procedure and who are at high for wounddehiscence.

Study design

Open randomised controlled trial that will be performed in the Radboud University Medical Center Nijmegen, with a sample size of 450 (α = 0,05; 1- ß = 0,8).

Intervention

In the experimental group Prevena* Incision Management System is applicated in clean closed surgical incisions.
In the controlgroup a simple cotton wounddressing (care as usual) is applicated in clean closed surgical incisions.

Study burden and risks

allergy for the wounddressing
If necessary about 20 minutes extra time (excl. travel time) when the patient has to visit the out patient clinic.

Contacts

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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
* at least one risk factor for wound dehiscence
- chronic obstructive pulmonary disease
- diabetes mellitus
- peripheral artery disease
- body mass index >= 30
- Active smoker
- Radiotherapy in history
- Earlier surgery in the same area
AND the patient undergoes one of the following elective sugical procedures:
o abdominal surgery through median laparotomy,
o vascular surgery through median laparotomy, upper leg and/or lower leg
o orthopedic surgery: hemipelvectomy, total knee replacement
o plastic surgery through a transverse suprapubic incision.

Exclusion criteria

incompetence
open fracture
fistulas in the area of the incision
simultaneous participation in another study

Study design

Design

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

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-02-2015
Enrollment:	450
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	12-02-2015
Application type:	First submission
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	NL51649.091.14