Treatment of subcutaneous abdominal wound healing impairment after surgery without fascial dehiscence by Vacuum-Assisted Closure® (V.A.C. ® SAWHI-Study) versus standard conventional wound therapy

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The primary objective of this multicenter, parallel design, prospective, randomized clinical trial, with repeated observations over time, is to compare the clinical, safety, and economic outcomes of V.A.C.® Therapy and SCWT based on an open...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON35758

Source
ToetsingOnline

Brief title
SAWHI study: VAC2010-56

Condition

- Other condition
- Skin and subcutaneous tissue therapeutic procedures

Synonym
NA

Health condition

onderhuids abdominale wondhelingsstoornis zonder fasciedehiscentie na operatie

Research involving

Human

Sponsors and support

Primary sponsor: University of Witten/Herdecke
Source(s) of monetary or material Support: KCI Europe Holding BV en KCI Kinetic Concepts San Antonio Texas;USA

Intervention

Keyword: Abdominal Wounds, VAC

Outcome measures

Primary outcome

The primary objective of this multicenter, parallel design, prospective,

randomized clinical trial is to compare the clinical safety and economic

outcomes of VAC therapy and SCWT in postsurgical abdominal wound healing

impairments without fascial dehiscence.

Secondary outcome

Secondary endpoints are related to a number of wound healing variables

(re-opened wound, wound size reduction), safety and quality of life.

Study description

Background summary

To treat wounds, normally many different types of wound dressings are being used. It is therefore considered the current standard therapy. Another therapy used for wound healing is VAC ® Therapy . VAC ® stands for Vacuum Assisted Closure ®. VAC ® Therapy is a system that uses controlled negative pressure (vacuum) to promote wound healing.

The KCI VAC ® Therapy * is used worldwide for many years for treating wounds

As healing takes place over a longer period of time from the acute (hospital) to the post-acute situation (eg home care), this study compares the effects of KCI VAC ® Therapy * compared to standard wound care (SCWT) during this process.

Study objective

The primary objective of this multicenter, parallel design, prospective, randomized clinical trial, with repeated observations over time, is to compare the clinical, safety, and economic outcomes of V.A.C.® Therapy and SCWT based on an open abdominal wound (also known as: subcutaneous abdominal wounds with healing impairment) after surgery without fascial dehiscence. The primary outcome to be observed in this study is time to complete open abdominal wound closure by Day 42 and confirmed closure after 14 consecutive days.

Study design

Multicenter, randomized controlled, clinical superiority trial

Intervention

Either VAC or conventional wound therpay (through randomization).

Study burden and risks

No additional risks. All risks are general, applicable for all wounds and wound treatments:

• Pain during debridement
• stinging / burning / pain in wound care dressing
* wound does not close

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

There are 2 categories of Subjects with distinct post-surgical open abdominal wound diagnoses that will qualify for this study:
• Subjects with primarily closed post-surgical abdominal wounds without fascial dehiscence that develop a spontaneous wound dehiscence or require an active reopening of the wound by the attending physician;• Subjects with open post-surgical abdominal wounds without fascial dehiscence that cannot be closed by primary intention and require further treatment to achieve permanent closure

Exclusion criteria

Pregnant;Dehiscence of the abdominal fascia ;Any pre-existing or ongoing organ system failure;Active signs or symptoms of Abdominal Compartment Syndrome

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-11-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	Vacuum-Assisted Closure® (V.A.C.) Therapy
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-08-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-02-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-09-2012
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL36083.068.11
Other	not yet done, after approval