Wountherapy in patienten with a sinus pilonidalis using a VAC-therapie versus Kerlix-gauze.

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To show the differrence of total healing of wound between two therapies, VAC and gauze-therapy, in patient with a sinu pilonidalis after chirgical intervention.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Tissue disorders NEC
Study type	Interventional

Summary

ID

NL-OMON34347

Source
ToetsingOnline

Brief title
WOVASP

Condition

- Tissue disorders NEC
- Hepatobiliary neoplasms malignant and unspecified
- Vascular disorders NEC

Synonym
Open wound

Research involving
Human

Sponsors and support

Primary sponsor: Rijnland Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Sinus polinidalis, VAC-therapy, Woundcare/therapy

Outcome measures

Primary outcome

• Time to complete healing of the woundwondgenezing

• Volume/area reduction after 3-6 weeks.

Secondary outcome

- QOL

- Pain

- Bacterial load

Study description

Background summary

Vacuum-assisted wound closure, refers to wound dressing systems that continuously or intermittently apply subatmospheric pressure to the surface of a wound.
Subatmospheric pressure has multiple beneficial effects on wound healing in animal models. However, clinical evidence of its superiority over conventional wound dressing techniques for all wound types has not been not proven. The available randomized trials have significant heterogeneity in the nature of wounds treated and in primary and secondary end points, making rigorous comparisons difficult and limiting the ability to generalize their results.

Study objective

To show the differrence of total healing of wound between two therapies, VAC and gauze-therapy, in patient with a sinu pilonidalis after chirgical intervention.

Study design

Gerandomiseerde control trial.

Intervention

Not applicable

Study burden and risks

Not applicable

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

Patients with a sinus pilonidalis need to have an excision by operation

Age between 18-65 years.

Exclusion criteria

Patients with DM, Arteriele/venous disability's
Allergy to Alganaten/Kerlix
BMI>35

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-12-2011
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	05-07-2011
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL33958.058.10