post operative negatieve pressure therapy after pilonidal sinus excision.

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If negative pressure wound therapy reduces the period of wound healing with 2 weeks till 6 weeks, instead of 8 weeks (all are approximate values), it can be the standard therapy in the future.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Skin and subcutaneous tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33917

Source
ToetsingOnline

Brief title
the SiPiVAC trial: the Sinus Pilinodalis Vacuum trial

Condition

- Skin and subcutaneous tissue therapeutic procedures

Synonym
pilonidal sinus, the jeep's disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: indien de zorgverzekeraar de vacuum wond therapie niet vergoed levert KCI medical (de fabrikant) het kosteloos ter voorkoming van byas.

Intervention

Keyword: negative pressure, pilonidal sinus, vacuum therapy

Outcome measures

Primary outcome

Primary parameters:

- short term parameter: wound size (length, broadth, depth) after 14 days

compared with day t=0 (surgery date)

- long term paramater: number of days to total wound healing

Definitions:

- total wound healing is wound depth of 0 mm

Secondary outcome

Secundary parameters:

- cumulatief recurrancepercentage after 6 maanden
- amount off days till full function of the patient after surgery
- painscore (VAS)
- woundcomplications: infection, abces of bleeding

- (technical) problems with the VAC-system

- percentage of patiënts stopping with VAC-therapie before 14 days

Definities

- Infection is defined as a bacterial infection causing antibiotics use.

- An abces of bleeding is scored if surgical intervention is necessary.

Study description

Background summary

The biggest problem of pilonidal sinus surgery with secondary wound healing is the long time it takes to heal the wounds.
The population of patients is young and active and the place of the wound is annoying. The healing of the wound is slow and therefore the patient can not work or go to school for a long time. The woundmanagement with standard bandages is considerd to be difficult by the patients.
Because we have good results with negative pressure wound therapy and we think that especially this population has benefit of a quick healing result, we designed this study.

Study objective

If negative pressure wound therapy reduces the period of wound healing with 2 weeks till 6 weeks, instead of 8 weeks (all are approximate values), it can be the standard therapy in the future.

Study design

It is a prospective randomized trial (1:1). The diagram shows the following steps(attachment 1)

All adult patients have to read teh information form and sign the approvel form. If the patient has the correct criteria the history and fysical exam is performed by the physcian and written down on the intake form.

The randomisation is centralized and takes place after consulting the study director.

Both study groups get the same surgery only the type of woundmanagment differs in the first two weeks.

The wound is measured, the name of the surgeons is written down and complications are documented on the operation form. The same form is used to determine the hospital stay and possible other complications during stay.

The first 2 weeks the patient is controlled twice in the hospital by the physician (day 7 and 14) and/or the wound nurse (day 3, 7, 10, 14). In case of negative pressure wound therapy the wound nurse changes the wounddressing. All the findings like wound measurements and pain score are written down on the control form. The negative pressure wound therapy ends on day 14, from that moment both groups are treated the same.
14 days of negative pressure wound therapy is based on literature findings and is considered to be an acceptabel period for the patient. After this period the activity of the patients grows so even the portable system we use can be annoying.

After 14 days the patient is seen weekly by the physician till the wound has healed. The last planned visit is after 6 months to check for recurrence.

Intervention

vacuum wound therapy for 2 weeks.

Study burden and risks

We expect minimal extra burden or risk with this treatment based on literature and our own findings in the clinic. This is futher explained in the study protocol.

A faster woundhealing, like we observed in the clinic, is only a benefit for this patient group.

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

Inclusion Criteria ;- 18 years or older, mentaly capable of making decision
- symptomatic sinus pilonidalis
- intention to undergo surgery
- written informed consent

Exclusion criteria

Exclusion Criteria;- severe language problem (dutch)
- abces sinus pilonidalis
- recurrent sinus pilonidalis after former excision
- too little space to insert the vacuumsponge (<3 cm from anus)
- severe transportation problem of the patient (do to handicap)

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:	Recruitment stopped
Start date (anticipated):	01-09-2009
Enrollment:	132
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	28-07-2009
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL25724.101.08