Rinsing of contaminated postoperative oncological wounds with tap water or an antiseptic agent * a randomized controlled clinical trial

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Determine whether there is a difference in the reduction of bacterial contamination between tap water and antiseptic agent (AdvaCyn) of contaminated postoperative oncological wounds.By using the Visual Analogue Score (VAS score), to measure the…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46491

Source
ToetsingOnline

Brief title
Rinsing of contaminated postoperative oncological wounds.

Condition

- Other condition

Synonym
contaminated wounds, wondbeslag

Health condition

gecontamineerde wonden na chirurgie van maligne aandoening

Research involving

Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: AVL polikliniek E5900

Intervention

Keyword: antiseptic agent, contaminated wounds, Rinsing, tap water

Outcome measures

Primary outcome

Number of microorganisms

Pain

Odour

Dropout

Secondary outcome

bleeding

infection

Study description

Background summary

At the AVL outpatient clinic treatment of oncological wounds consists of 2 standard treatments: 1) rinsing wound with tap water and 2)rinsing wound with antiseptic agent.

There is no guideline to suggest which treatment is most effective in reducing micro-organism contamination within the wound.. It is unclear which treatment is experienced by the patient as most comfortable by patients. There is no scientific evidence which suggest one treatment is better than the other. Although rinsing with tap water is significantly cheaper.

If both treathments result ina similar contamination reduction it would be

adviseble to choose tapwater as this is most cost-efficient. So this proves the relevance of the aim of this study.

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Study objective

Determine whether there is a difference in the reduction of bacterial contamination between tap water and antiseptic agent (AdvaCyn) of contaminated postoperative oncological wounds.

By using the Visual Analogue Score (VAS score), to measure the effect on odour reduction during the 2 week treatment period.

By using the Visual Analogue Score (VAS score), to measure the effect on the pain sensation before, during and after treatment.

Study design

The treatments consists of two different methods. These treatments are already in use within this specific patientgroup. patients are required to attend 2x 30 minute consultations. During consultation a culture, pain score + a scent score will be taken. the wound will be rinsed with 150cc water of antiseptic agent. There will also be one telephone consultation whereby a pain, odour, bleedingand infection checklist will becarried out.

The above guidelines have been encorpurated is standart care guidelines.

Intervention

Rinse wound 2 x a day with tap water.
Rinse wound 2 x a day with antiseptic agent (Advacyn).

Study burden and risks

It is about 2 treatment methods that are already appropriate for these patients.

The burden for the patient is:
2 x 30 minutes consultation. During this consultation, a culture is taken, asked for pain and scent score and rinsed with 150 cc water or antiseptic agent.
1 x 10 minutes telephone consultation. During this consultation, pain and odour experience is questioned and if there has been bleeding or infection.

Upside down now also belong to regular care.

It consists of two different treatment methods.

The requirement for the patient is two consultations, duration 30 minutes. This treatment is already in use within this specific patientgroups

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 older > 18 years.
Wound dehiscence of at least 2 cm long or deep.
Wound in the abdomen, inguinal, breast, perineum or extremities.
Between two weeks and three months postoperatively.
Wound must be free of necrosis.

Patient is willing and physically and psychologically able to follow instructional protocol.

Exclusion criteria

Smoking at time of start treatment with rinsing.
Antibiotics use rinsing less than three days before starting.
Not able to assess and sign independently informed consent.
Detrimental or detectable presence of malignancy
Diabetes mellitus

Study design

Design

Study phase:	3
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):	01-02-2018
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	24-01-2018
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van

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	NL63459.031.17