

Tapwater versus chlorhexidine

Incidence of secondary infection after woundcleaning

Published: 19-07-2011

Last updated: 29-04-2024

Can a difference be measured in incidence of secondary wound infection after wound cleaning with either tap water or chlorhexidin?Hypothesis: After use of tap water in wound cleaning, no difference in incidence of secondary wound infection compared...

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

Summary

ID

NL-OMON38157

Source

ToetsingOnline

Brief title

Tapwater versus chlorhexidine for woundcleaning

Condition

- Skin and subcutaneous tissue disorders

Synonym

(secondary) wound infection or inflammation

Research involving

Human

Sponsors and support

Primary sponsor: HagaZiekenhuis

Source(s) of monetary or material Support: HAGA Ziekenhuis

Intervention

Keyword: chlorhexidine, secondary wound infection, tapwater, wound cleaning

Outcome measures

Primary outcome

The endpoint of this study is the percentage wound infection after wound treatment with stitches or tissue adhesive in the group cleaned with tap water and in the group cleaned with chlorhexidine.

Secondary outcome

Do patients prefer cleaning with tap water or chlorhexidine?

Is wound healing different in wounds cleaned with tap water or chlorhexidine?

Is there a difference in experiencing pain between cleaning with tap water or chlorhexidine?

Study description

Background summary

In medical practice there are several ways to disinfect wounds in order to minimize the chance of infection. Wounds can be disinfected with iodine, NaCl, chlorhexidine or tapwater.

Emergency departments are being visited a lot for wounds. In the USA 7-8% of emergency department visits exist of patients presenting with wounds. The emergency department of the Haga Hospital is visited by 6 patients with a wound a day. Contaminated wounds have an incidence of infection as high as 20%. Wounds in general have 4,5-6,3% chance of infection.

At the emergency department of HAGA Hospital wounds are normally cleaned with chlorhexidine before they are stitched or treated with tissue adhesive. But there is reason to believe chlorhexidine can complicate wound healing by disturbing cells that are necessary for wound healing.

Chlorhexidine is also expensive, 6 euro a liter. A bottle chlorhexidine may only be used 24 hours after opening of the bottle.

Iodine is not an alternative, because it disturbs neutrophil leukocytes, that are necessary for wound healing.

An alternative for chlorhexidine could be tap water, this is easy to use and cheaper than chlorhexidine. Tap water costs 0,00121 - 0,00210 euro a liter. Tap water is already used as a irrigant in a lot of hospitals, for example Erasmus MC.

A lot of studies have been performed after the use of tap water and the incidence of wound infection, and they show tap water is a save alternative to iodide and NaCl. Chandra Bansal investigated the difference in incidence after wound cleaning with tap water and NaCl in children and found no significant difference. (RR 1.07, 95% CI 0.43 to 2.64; P = 0.88)

Fernandez et al wrote a systematic review with a result that tap water might even decreases chance of wound infection. (RR 0.55, CI 0.31 to 0.97).

Cochrane has a review called *Comparison of tap water with normal saline*, that consists of 3 trials (Angeras 1992; Godinez 2002; Moscati 2007) that studies stitch wounds. The group with wounds cleaned with tap water showed a significant reduction in secondary wound infection.(RR 0.63, 95% CI 0.40 to 0.99; P = 0.05).

No comparing studies that study the outcome of disinfection with chlorhexidine compared to tap water have been found. Also we haven't been able to find a study that supports the use of chlorhexidine. We searched PubMed, UptoDate and The Cochrane Library.

Study objective

Can a difference be measured in incidence of secondary wound infection after wound cleaning with either tap water or chlorhexidin?

Hypothesis: After use of tap water in wound cleaning, no difference in incidence of secondary wound infection compared to chlorhexidin can be measured.

Secondary endpoints:

Do patients prefer cleaning with tap water or chlorhexidine?

Is wound healing different in wounds cleaned with tap water or chlorhexidine?

Is there a difference in experiencing pain between cleaning with tap water of chlorhexidin?

Study design

Patients that are presenting themselves at the emergency department are being asked by the triage-nurse to participate in the study and receive written information. They can use the time in the waiting room to read the information and decide whether or not to give permission. If a patient declines participation, the patient receives the usual treatment, according to the existing wound protocol, used at the surgery department. This means wounds of these patients are cleaned with chlorhexidin.

If the patient does give permission, the wound is being cleaned in the way according to the randomization, before it is being closed with tissue adhesive

or stitches. If the patient needs stitching, the wound is as usual being anaesthetized with lidocain 1%. The wound is being stitched while the doctor is wearing non-sterile gloves and with a disposable sterile suturing material. The patient gets an appointment to remove the stitches and to check the wound for infection. In general this appointment will be 7 days after stitching of the wound. Depending on the availability of researcher and patient this varies from 6-8 days after stitching depending on localization of the wound. The patient can bring the information letter which holds the researchers contact information, to enable the patient to contact the researcher in case of questions or if there's any doubt about occurring infection. The general practitioner will be called and informed about participation. 7 days after stitching the stiches will be removed in a room on the emergency department and will be checked for infection.

Patients medical file will be used to collect characteristics of the wound, such as time passed between occurring of the wound and treatment, and the kind of injury. Patients will be asked to number the pain during treatment, this is the painscore. The patient has to give a number between 1 to 10, 1 is no pain at all and 10 is the most severe pain ever. This system will be explained to the patient. The researcher will write the number on the checklist. It will be written down whether the wound borders are closed. Also the patient will be asked whether he or she had a preference for treatment with chlorhexidine or tapwater. This data will be written on a specially designed checklist.

Also a picture will be taken of all wounds, which doctor A.E. Hoek will take a look at in order to speak out a second opinion. When there is a discrepancy between the first finding by the researcher and the judgement of dr. Hoek, a third doctor will be asked for his/her opinion. The third doctor will be the attending Emergency Physician. If the opinion of the attending Emergency Physician is that there infection has occurred and so antibiotics have to be prescribed, the patient will be called immediately.

In case of infection the Emergency Physician will be asked to take a look at the wound in order to prescribe antibiotics.

During wound check there will be asked if there have been signs of infection earlier that week, and if the patient has seen his general practitioner. If that's the case, there will be asked permission to contact the general practitioner to collect data.

Infection is the contamination of tissue with parasites, fungi, bacterias or viruses. Patients in this study could get a local infection at the site of the wound. I will check for the following characteristics of infection:

- Tumor or swelling,
- Rubor or redness,
- Dolor or pain,
- Calor or warmth,
- Functio laesa or loss of function,
- Pus or abscess

The wound is being categorized in one of the following 4 categories.

0 = No signs of inflammation.

1 = The wound shows signs of inflammation, showing normal physiological healing: redness <4mm from woundborder, swelling not crossing the physiologic redness, pain not increased compared to at presentation, warmth not crossing the physiological redness, loss of function not increased compared to presentation, no matter in what combination, and therefore needs no treatment.

2 = The wound shows signs of infection redness >4mm from woundborder, swelling crossing the physiologic redness, pain increased compared to at presentation, warmth crossing the physiological redness, loss of function increased compared to presentation and therefore needs treatment. One sign or a combination of more signs is considered an infection.

3 = The wound has pus or abscesses and needs treatment.

Categories 2 and 3 will be considered secondary infection.

Intervention

Instead of wound cleaning with chlorhexidine, the wound will be irrigated with tap water that is being sucked into a sterile syringe.

Study burden and risks

Burden is minimal and exists of an appointment in the hospital to remove stitched and/or wound inspection.

Contacts

Public

HagaZiekenhuis

Leyweg 275
Den Haag 2545CH
NL

Scientific

HagaZiekenhuis

Leyweg 275
Den Haag 2545CH
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients aged 18 years and older.

Patients attending the emergency department of the Haga Hospital with a skin laceration that requires tissue adhesives or sutures.

Patients that are able to visit the Haga Hospital 6-8 days after primary visit for wound inspection.

Patients do speak Dutch

Exclusion criteria

Patients aged under 18 years.

Patients with hypersensitivity to chlorhexidine.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-08-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO	
Date:	19-07-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Approved WMO	
Date:	06-03-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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
EudraCT	EUCTR2011-002670-24-NL

Register

CCMO

ID

NL36661.098.11