A comparison of skin preparation techniques: povidine-jodine with alcohol versus chlorhexidine with alcohol in forefoot surgery

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The main objective of this study is to compare the efficacy, in skin antisepsis in forefoot surgery. Therefore we will compare povidine-jodine with chloride-hexidine both soluted in 70% alcohol.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bone and joint therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON37348

Source
ToetsingOnline

Brief title
povidine-jodine versus chlorhexidine in forefoot surgery

Condition

- Bone and joint therapeutic procedures

Synonym
hallux rigidus, hallux valgus

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chloridehexidine, forefoot, povidin-jodine, skin

Outcome measures

Primary outcome

The primary end point of this study is the number of positive swab cultures. If

positive there ill be a qualitative and quantitative analysis.

Secondary outcome

The secondary outcome of the study is the number of post-operative wound

infections till 6 weeks postoperative and allergic event against the skin

preparative.

Study description

Background summary

Feet are a part of the human body which are usualy often cantominated wih bacterial species.
In the past several publications have compared chloride-hexidine Alcohol with povidone-iodine. In these studies chloride-hexidine seems in favour for skin antisepsis.
So far there hasn*t been a research project which compares chloride-hexidine Alcohol versus povidone-iodine Alcohol.
Our purpose is to evaluate the efficacy of chloride-hexidine soluted in 70% alcohol and povidine-iodine sluted in 70% alcohol in skinpreparation in forefoot surgery

Study objective

The main objective of this study is to compare the efficacy, in skin antisepsis in forefoot surgery. Therefore we will compare povidine-jodine with chloride-hexidine both soluted in 70% alcohol.

Study design

All patient at our outpatient clinic fulfillling the inclusion criteria will be informed about the study.
They will be informed again and asked to participate during a second visit. In case of participation the patient will sign the informed consent.
Prior to skin preparation swaps will be taken from the webspace of the first en second toe and from the place where we will incise the skin.
After skin preparation and after wound closure the same procedure (skinswaps from wapsapce and incision place) will be repeted.
No surgical drapes will be used.
All swabs will have a quantative and qualitative analysis.
Visits will be done 1 day, 2 weeks and 6 weeks post-operative.
Woundinfections will be counted according to the PREZIES criteria.

Intervention

n.v.t.

Study burden and risks

There are no extra visits than for pateints undergoing the same surgery but not participating in this study.
There are no other risk than related to the operation.

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

informed consent
age> 18
indication for hallux valgus correction or arthrodesis of the MTP 1 joint

Exclusion criteria

active infection
allergic for jodine and/or chlorhexidine
skindefect
bloodcoagulopathy

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	26-03-2013
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	25-10-2012
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ClinicalTrials.gov	NCT:identificatienummervolgt
CCMO	NL39133.100.12