Prospective randomised trial using Integusealâ as microbial sealant for arterial bypass surgery on lower extremities

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This prospective randomised study has the primary objective to prove a reduction of postoperative wound infections after direct preoperative use of a microbial sealant in the form of Integuseal for vascular procedures on lower extremities. We aim at...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON32841

Source
ToetsingOnline

Brief title
ITT (Integuseal trial)

Condition

- Bacterial infectious disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Postoperative wound infections

Research involving
Human

Sponsors and support

Primary sponsor: Alysis Zorggroep
Source(s) of monetary or material Support: Kimberly-CLark industries

Intervention

Keyword: Arterial bypass surgery, Infection prophylaxis, Integusealâ microbial sealant, Postoperative wound infections

Outcome measures

Primary outcome

Postoperative woundinfections

Secondary outcome

Costs of the use of Integusealâ

complications during hospital stay

Study description

Background summary

Postoperative woundinfections are responsible for approximately 25-38% of all in-hospital infections that occur after surgery. A postoperative woundinfection occurs in 2-5% of patients. The woundinfection rate after peripheral vascular procedures is approximately 6%.
Due to these woundinfections, duration of treatment and hospital admission increases and costs are higher.
This consequently increases the risk for other complications.
Infection prevention has become a big issue in surgery. Current measures to prevent wound infections are asepsis of the operation area, antisepsis of the surgeons hands, antimicrobial prophylaxis, management on the operation rooms, operation techniques, but also postoperative woundcare. Besides these current measures, in some clinics antiseptic impregnated incision foil is being used, however it did not lead to a significant reduction in wouind infections.

A new technique using a microbial sealant (Integuseal) applicated preoperatively with a sponge applicator, would have positive results on the reduction of postoperatieve woundinfections.

Study objective

This prospective randomised study has the primary objective to prove a reduction of postoperative wound infections after direct preoperative use of a microbial sealant in the form of Integuseal for vascular procedures on lower extremities. We aim at a reduction in wound infections of 50%.

Secundary we will study the costs of the use of Integuseal

Study design

Prospective randomised trial (comparable groups)
Population of 200 patients; 100 in the intervention study group and 100 in the control group.
Conventional infection prevention measures versus conventional measures WITH use of Integuseal preoperative.

Inclusion criteria: Planned arterial bypass procedure with autologue or prosthetic graft at or below the groin (inguinal level). Operation classified as 'clean' procedure following criteria of the US national research council group.
Exclusion criteria: Secondary procedures or vascular procedures above the groin (inguinal level)

Woundevaluation for wound infection will be done at postoperative day 2,4,6,8,10 and 14 accoring to the SOuthampton Wound Assessment Scale.

The last woundevaluation and the end of this study will be at two weeks after hosptal dismission.

Costs of the use of Integuseal are being evaluated

Intervention

Application of a layer of Integuseal (Cyanoacrylate) from a ready to use applicator preoperative before incision. Polymerisation immobilises the bacteries that survived the conventional skin preparation. This way there will be less contamination of the wound.

Study burden and risks

Burden: a possible extra visit for woundevaluation when the patient is dismissed within two weeks after surgery.
There will be no unnecessary hospitalisation en patients will not be witheld of any conventional medical care.

So far no healththreatening risks are described of Integusealâ

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

Planned supragenual of infragenual peripheral arterial bypass procedures with autologue or prosthetic graft

Exclusion criteria

Secundaire procedures and suprainguinal procedures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	17-06-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL25592.091.08