PREVENTION OF SURGICAL SITE INFECTION AT THE GROIN AFTER FEMORAL ARTERIAL EXPOSURE USING LOCAL GENTAMYCIN SPONGE PROSPECTIVE, RANDOMISED, CONTROLLED TRIAL

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The aim of this study is to test the hypothesis that a gentamicin-collagen sponge reduces the incidence of surgical site infection (SSI) in patients undergoing inguinal dissection for vascular disease

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Vascular therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON38160

Source
ToetsingOnline

Brief title
Implantable Gentamycin sponge and surgical site infection at the groin

Condition

- Vascular therapeutic procedures

Synonym
Surgicale site infection, wound infection

Research involving

Human

Sponsors and support

Primary sponsor: Atrium Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: garacol, gentamycin, SSI (Surgical Site Infection)

Outcome measures

Primary outcome

The incidence of surgical site infection (SSI), including prosthetic graft

infection classified according to Szilagyi, through 30 days postoperatively by

a committee blinded to study allocation

Secondary outcome

Length of the incision (measured postoperatively and photographed).

Quantitative microbial count of skin flora immediately post-incision between

two treatment groups when purulent fluid evacuates from the wound. (Isolation

of bacteria in colony forming units (CFU))

Creatinine, Leukocyte numbers and CRP measured at day 1 post-operative, at

discharge and at 2 weeks.

Bypass patency was confirmed by noninvasive hemodynamic Doppler studies on the

first postoperative day and by duplex 6 weeks after index operation.

Postoperative complications are recorded.

Length of hospital stay.

Re-admission and reoperation.

Use of intravenous or oral antibiotic during hospital stay and at home

Study description

Background summary

Despite the routine use of prophylactic systemic antibiotics, inguinal surgical site infection still occurs in 4-44% in patients undergoing femoral exposure for central or peripheral arterial disease and is associated with significant excess morbidity, mortality, and costs. A large, 2-center, randomized trial in Sweden reported in 2005 that a gentamicin-collagen sponge, a surgically implantable topical antibiotic, reduced surgical site infection by 50% in patients undergoing cardiac bypass surgery.
The aim of this study is to test the hypothesis that a gentamicin-collagen sponge reduces the incidence of surgical site infection (SSI) in patients undergoing inguinal dissection for vascular

Study objective

The aim of this study is to test the hypothesis that a gentamicin-collagen sponge reduces the incidence of surgical site infection (SSI) in patients undergoing inguinal dissection for vascular disease

Study design

The study is designed as a prospective, randomized, controlled trial

Intervention

The study arm will receive the implantable gentamicin collagen sponge and the control arm will not receive a sponge at the end of the vascular procedure before closing the groin

Study burden and risks

1 extra visit to the out-patient clinic
possible allergic reaction to gentamicin
possible reduction of woundinfections

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

All patients undergoing femoral incision for primary arterial repair.
Patients are 18 years or older, and both sexes can participate.
Signed informed consent

Exclusion criteria

Patients known with a sensitivity or allergy to gentamicin.
Patients pregnant or breast feeding.
In case of bilateral groin dissection for vascular surgery, the left groin is excluded.
Patients undergoing femoral incision for endovascular procedures

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-04-2012
Enrollment:	608
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Garacol
Generic name:	gentamicin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	19-03-2012
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	EUCTR2011-001786-40-NL
CCMO	NL36728.096.11