Antibiotic prophylaxis and prevention of wound infections following implant removal after foot, ankle and lower leg fractures

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

Summary

ID

NL-OMON44330

Source
ToetsingOnline

Brief title
WIFI-trial

Condition

- Fractures
- Skin and subcutaneous tissue disorders
- Bone and joint therapeutic procedures

Synonym
postoperative wound infection

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Antibiotic profylaxis, Implant removal, Wound infection

Outcome measures

Primary outcome

The primary outcome is the incidence of wound infection (within 30 days after implant removal) as defined by the criteria applied by the CDC and diagnosed by the attending physician.

Secondary outcome

Secondary outcomes are health-related quality of life (as measured by the EQ-5D), functional outcome (assessed with the Lower Extremity Functional Scale), patient satisfaction (measured by a ten-point Visual Analog Scale), several treatment and function related items (including amongst others, number of visits to the general practitioner and use of home care organizations) measured at 30 days and 6 months postoperatively, as well as costs (e.g. production losses due to sick leave). In addition, the incidence of micro-bacterial growth in cultures taken peroperatively (evaluation between patients with and without antibiotic prophylaxis) and diversity of micro bacterial growth in postoperative wound infection will be documented.

Study description

Background summary

Imagine: a year ago you broke your ankle and were operated on. Full recovery took many weeks. Now the plate is removed, supposedly a minor procedure. However, 3 days after the operation you get a wound infection, necessitating a hospital admission, a re-operation and antibiotics. The healing process takes several weeks, with all its inconveniences, like changing wound dressings and absence from work.
This research proposal is about prevention of such infections.
Patients with lower leg fractures are treated either conservatively with a cast or with the use of implants (osteosynthesis material) to restore anatomy and function. The implant can be removed at a later stage. The indications for implant removal in adult patients include symptomatic hardware (i.e. pain, thin overlying skin and restricted motion), failure of the implant (breakage, loosening), or a persistent infectious complication of the index procedure (infection or fistula). Some patients choose to have implants removed for no specific reason.
In the Netherlands each year about 18,000 surgical implant removals are performed after fracture healing, of which 30-80% from the foot, ankle and lower leg region. In contrast to surgical fracture fixation with metal implants, antibiotic prophylaxis is not routine practice prior to implant removal. This is because, according to the Centres for Disease Control and Prevention (CDC) classification of surgical wounds, implant removal is considered a *clean* procedure. For *clean* procedures the rate of wound infections should be less than 5% and no benefit of preoperative antibiotics has been seen. However, rates of 12% following implant removal, specifically after foot, ankle and/or lower leg fractures, have been observed both by us and others. This implicates that implant removal should not be seen as *clean* procedure but rather as *clean-contaminated* or in some patients even as a *contaminated* procedure. Consequently, preoperative antibiotics might be beneficial to reduce the incidence of infectious complications. Use of a single gift of prophylactic antibiotics has been shown to be as efficient as repeated prophylactic gifts. Moreover, a single gift is preferred since it avoids development of antibiotic resistance. In current practice, surgeons decide upon themselves if antibiotics are administered preoperatively, which is based on expert opinion as no evidence based guideline exists. This results in undesirable practice variation.

Study objective

In light of the above, our objective is to study the (cost-) effectiveness of a single intravenous gift of antibiotic prophylaxis with a first

generation cephalosporin prior to implant removal following surgical fixation of foot, ankle and/or lower leg fractures. We will examine the effects in terms of the rate of postoperative wound infections (primary outcome), health related quality of life, functional outcome and health care costs (secondary outcomes). In addition, we will create an evidence based guideline.

Study design

Multicentre, double-blind, randomized, placebo controlled trial. The study will be conducted according to the principles of the Declaration of Helsinki, the Medical Research Involving Human Subjects Act (WMO), Good Clinical Practice Guidelines (GCP) and other applicable (inter)national regulatory requirements.

Intervention

Patients will be randomly assigned to implant removal with administration of a single dose intravenous antibiotic prophylaxis (cefalozin) or a matching 10 cc NaCl 0.9% by use of a web-based randomization site. The vial will administered 30 minutes pre-operatively (t=0). During surgery a bacterial swab will be taken from the implant. Patients will return at least once to the outpatient clinic postoperatively as usual (t<30 days).

Study burden and risks

The risks in this study are acceptable for the patients participating in this study, as cephalozin is already used as a prophylactic antibiotic in current practice in open reduction and internal fixation of lower leg, ankle and foot fractures.
The prolonged supervision of patients does not harm patients in any way and can only contribute to better patient management.

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

Implant removal in foot, ankle and lower leg in patients *18 years and *75 years of all ethnic backgrounds

Exclusion criteria

- Removing and re-implanting material in the same session
- Implant removal due to active infection
- Implant removal due to a (plate) fistula
- Current antibiotic treatment
- Allergy to cephalosporines

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-11-2014
Enrollment:	500
Type:	Actual

Medical products/devices used

Product type:	Medicine
Generic name:	Cefazolin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	07-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	23-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-03-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	10-04-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-05-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	16-09-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	

Date:	20-10-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-03-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	EUCTR2014-000124-14-NL
CCMO	NL49413.018.14