Voorkomen van wondinfecties bij verwijderen van lichaamsvreemd materiaal onder de knie.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28685

Source
NTR

Brief title
WIFI-trial

Health condition

Implant removal
Wound infection
Antibiotic prophylaxis
Functional outcome

Verwijderen van osteosynthesemateriaal
Postoperatieve wondinfectie
Antibiotca profylaxe
Functionele uitkomst

Sponsors and support

Primary sponsor: Academisch Medisch Centrum Amsterdam
Source(s) of monetary or material Support: AO Nederland

Intervention

Outcome measures

Primary outcome

The primary outcome is the incidence of wound infections (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

In the Netherlands about 18,000 surgical procedures with implant removal are annually performed after fracture healing, of which 30-80% concern the foot, ankle and lower leg region. For clean surgical procedures, the rate of postoperative wound infections should be less than 5%. However, rates of 12% following implant removal, specifically after foot, ankle and lower leg fractures are reported. Currently, surgeons decide individually if antibiotics prophylaxis is given, since no guideline exists. This leads to undesirable practice variation.

Therefore, we propose a double-blind, placebo-controlled RCT in patients scheduled for implant removal following a foot, ankle or lower leg fracture, to assess the (cost-)effectiveness of a single gift of antibiotic prophylaxis. Primary outcome is a wound infection within 30 days. Secondary outcomes are quality of life, functional outcome at 30 days and 6 months after implant removal and costs. With 2x170 patients a decrease in postoperative wound infections from 12% to 3.3% (expected rate in clean-contaminated elective orthopedic trauma procedures) can be detected (Power=80%, 2-sided alpha=5%).

If our assumption that prophylactic antibiotics prior to implant removal reduces the infectious complication rate, is confirmed by our RCT, this will offer a strong argument to adopt a single

gift of antibiotic prophylaxis as standard practice of care. This will reduce the incidence of wound infections and consequently will lead to less physical and social disability and health care use. A preliminary, conservative estimation suggests yearly cost savings of € 3.3 million per year.

Study objective

The incidence of postoperative wound infections following implant removal below the knee joint is lower in patients receiving a preoperative single gift of antibiotic prophylaxis compared to patients without antibiotic prophylaxis.

Study design

0 days, 30 days, 6 months

Intervention

Preoperative single gift of iv antibiotic prophylaxis (Cefalozin)

Contacts

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Eligibility criteria

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 type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2014
Enrollment:	500
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL4248
NTR-old	NTR4393
CCMO	NL47722.018.14

Study results