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

Gepubliceerd: 09-01-2014 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28685

Bron
NTR

Verkorte titel
WIFI-trial

Aandoening

Implant removal
Wound infection
Antibiotic prophylaxis
Functional outcome

Verwijderen van osteosynthesemateriaal
Postoperatieve wondinfectie
Antibiotca profylaxe
Functionele uitkomst

Ondersteuning

Primaire sponsor: Academisch Medisch Centrum
Amsterdam

Overige ondersteuning: AO Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

0 days, 30 days, 6 months

Onderzoeksproduct en/of interventie

Preoperative single gift of iv antibiotic prophylaxis (Cefalozin)

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-08-2014
Aantal proefpersonen:	500
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten