Wound Infections Following Implant Removal

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2gr of Cefazolin is effective as prophylaxis for surgical site infections following implant removal below the level of the knee.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20062

Bron
NTR

Verkorte titel
WIFI-2

Aandoening

Elective implant removal (IR) after fracture fixation below the level of the knee

Ondersteuning

Primaire sponsor: ZonMW
Overige ondersteuning: ZonMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Proportion of patients with a surgical site infection within 90 days

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Elective implant removal (IR) after fracture fixation is one of the most common procedures within the orthopaedic/trauma surgery. The rate of surgical site infections (SSIs) in this procedure is quite high, especially below the level of the knee. Antibiotic prophylaxis is not routinely prescribed, even though it has proved to lower SSI rates in other orthopaedic/ trauma surgical procedures.
Objective: The primary objective is to study the effectiveness of a single intravenous dose of 2g of cefazolin on SSIs after IR following fixation of foot, ankle and/or lower leg fractures. Secondary objectives are to study the cost-effectiveness of 2g of cefazolin preventing SSIs after IR, to study target-site antibiotic concentrations and tissue oxygenation, to identify underlying infections, and to identify independent predictors of SSI.
Study design: This is a multicenter, double-blind placebo controlled intervention study
Study population: Adult patients (>17 y/o) undergoing elective implant removal after fixation of a fracture of foot, ankle, lower leg or patella.
Intervention (if applicable): The intervention group receives 2g of cefazolin as preoperative antibiotic prophylaxis, the control group receives a placebo injection.
Main study parameters/endpoints: the main study parameter is the proportion of patients with a SSI.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participating in this trial does not propose additional risk to the patient compared to current practice. Cefazolin has proved to be safe and effective as preoperative antibiotic prophylaxis in this dose. The burden is low for most patients as extra visits to the hospital are not required and questionnaires will take approximately 60 minutes in total. Additional measurements are only applicable to a small proportion of participants at the Amsterdam UMC. For these patients, blood samples will be obtained during surgery, under general or regional anaesthesia and include 3-4 serum samples, 2 target-site blood samples and 2 target-site soft tissue samples. Moreover patients will undergo continuous subcutaneous tissue oxygen tension measurements and measurements of haemoglobin oxygenation in the local microcirculation of the contralateral foot. No extra visits to the outpatient clinic are required when participating in the trial.

Doel van het onderzoek

2gr of Cefazolin is effective as prophylaxis for surgical site infections following implant removal below the level of the knee.

Onderzoeksopzet

Start inclusion: January 2020
End of follow up: April 2023 (until 6 months after last IR)
Analysis: May 2023 – July 2023

Implementation: August 2023 – October 2023

Onderzoeksproduct en/of interventie

The intervention group receives 2g of cefazolin as preoperative antibiotic prophylaxis, the control group receives a placebo injection.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Aged between 18 and 75 years
- Scheduled for IR following fracture surgery of the patella, lower leg, ankle or foot

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Removing and re-implanting osteosynthetic material in the same session
- Active wound infection or (plate) fistula
- A medical history of serious peripheral vascular disease (≥ Fontaine III) Antibiotic treatment at time of IR for a concomitant disease or infection
- A medical history of severe hypersensitivity to penicillin or any other beta-lactam antibiotic

- Severe kidney insufficiency (eGFR < 35)
- Pregnancy and lactation
- Treatment with probenecid, anticoagulants
- Immunosuppressant use in organ transplantation or rheumatoid joint disease
- Insufficient comprehension of the Dutch/English language to understand the patient information to make an informed decision to participate

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	23-12-2019
Aantal proefpersonen:	732
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	09-01-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 54651
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8284
CCMO	NL71051.018.19
OMON	NL-OMON54651

Resultaten

Samenvatting resultaten
N/A