Wound Infections following Implant Removal below the level of the knee; the influence of 2g of prophylactic Cefazolin

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON54651

Source
ToetsingOnline

Brief title
WIFI-2

Condition

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

Synonym
surgical site infection; 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: implant removal, lower leg, prophylactic antibiotics, surgical site infections

Outcome measures

Primary outcome

the main study parameter is the number of SSIs

Secondary outcome

Secondary outcomes are the cost-effectiveness of 2g of cefazolin, the underlying mechanism of prophylactic antibiotics (target-site antibiotic concentrations and tissue oxygenation), underlying infections, and independent predictors of SSI.

Study description

Background summary

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.

Study 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

Intervention

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

Study burden and risks

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.

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

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

Exclusion criteria

- Removing and re-implanting osteosynthetic material in the same session - Active wound infection or (plate) fistula - Antibiotic treatment at time of IR for a concomitant disease or infection - A medical history of serious peripheral vascular disease (>= Fontaine III) - A medical history of severe hypersensitivity to penicillin or any other beta-lactam antibiotic - Severe kidney insufficiency (eGFR < 35) - Pregnancy - Treatment with probenecid (see SPC) - 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-02-2020
Enrollment:	732
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	15-10-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-12-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	07-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-03-2020
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-09-2020

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-05-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-06-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-08-2022
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl
Approved WMO Date:	10-01-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214

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Approved WMO Date:	16-05-2023
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20062
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2019-003105-10-NL
CCMO	NL71051.018.19
OMON	NL-OMON20062