TArget-Site Concentrations of prophylactic cefazolin in foot and Ankle surgery

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To analyze the difference in fT>MIC at the target site and infection rate for a single dose of 1 and 2g of cefazolin.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Fractures
Study type	Interventional

Summary

ID

NL-OMON46781

Source
ToetsingOnline

Brief title
TASCA-trial

Condition

- Fractures
- Skin and subcutaneous tissue disorders
- 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: volgt;beurs aangevraagd bij OTC en AMS

Intervention

Keyword: ankle, concentration, foot, prophylactic antibiotics

Outcome measures

Primary outcome

Primary outcome: fT>MIC at the 'target-site'

Secondary outcome

Secondary outcome: fT>MIC in serum, rate of SSI, correlation between fT>MIC and

infection

Study description

Background summary

The incidence of surgical site infections (SSI) in foot and ankle fracture surgery is high. Below the knee, 1g of prophylactic cefazolin seems to have no effect on the rate of SSI, even though it has proved to be successful in hip and knee procedures. When studying concentrations, the amount of cefazolin in tissue of the foot is up to 30 times lower than in the knee. This suggests that penetration of antibiotics in more distal parts of the lower limb might be impaired and a dose of 1g might not be sufficient. To link the concentration of antibiotics to the antibacterial effect one needs to know the time that the free proportion of antibiotics exceeds the minimum inhibitory concentration (fT>MIC). However, to the best of our knowledge, the target site fT>MIC has not been investigated in trauma/orthopedic surgery, let alone in foot and ankle. Analyzing the fT>MIC at the target site will provide us with more knowledge about the optimal dosing and effectiveness of antibiotic prophylaxis at the target site.

Study objective

To analyze the difference in fT>MIC at the target site and infection rate for a single dose of 1 and 2g of cefazolin.

Study design

Double blind, randomized controlled superiority trial.

Intervention

Group 1 receives a single dose of 1g of intravenously administered cefazolin, 30 minutes before surgery and group 2 receives a single dose of 2g of intravenously administered cefazolin, 30 minutes before surgery.

Study burden and risks

Participating in this trial does not propose additional risk to the patient compared to current practice. Both dosing cefazolin regimens (1g/2g) have proved to be safe and effective. Samples are all 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. 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

- >17 years old
- Undergoing open surgery of the foot or ankle

Exclusion criteria

- Antibiotic treatment within 7 days before the surgery
- An open fracture
- A medical history of an allergic reaction to a cephalosporin or severe reaction to penicillin, or any other *-lactam antibiotic
- Insufficient comprehension of the Dutch language to understand the patient information to make an informed decision to participate
- Kidney disease (eGFR <60 ml/min/1.73m^2)
- Pregnancy and lactation
- A medical history of Diabetes Mellitus or serious peripheral vascular disease (* Fontaine III)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO Date:	25-05-2018
Application type:	First submission
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	EUCTR2018-001106-28-NL
CCMO	NL65398.018.18