Multiple doses versus single dose of cefazolin to prevent periprosthetic joint infection after revision arthroplasty: a multicenter open-label, randomized clinical trial

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The aim of this multicenter open-label, randomized controlled trial is to investigate the superiority of 5 days (extended) versus a single dose of cefazolin prophylaxis in revision arthroplasty of the hip and knee.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Interventional

Summary

ID

NL-OMON48292

Source
ToetsingOnline

Brief title
REViSION

Condition

- Bacterial infectious disorders
- Bone and joint therapeutic procedures

Synonym
joint infection, prosthetic joint infection

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: antibiotic prophylaxis, PJI, Revision

Outcome measures

Primary outcome

The primary endpoint is the difference in proportion of infection-free implant survival between the study groups within 1 year of follow-up, as assessed by the independent Data Review Committee, in the mITT population.

Secondary outcome

The secondary objectives include the determination of the incidence, risk factors, treatment outcome and prognosis of SSI and PJI during follow-up. The safety and tolerance of the regimens, and the antimicrobial susceptibility patterns of microorganisms will be described. Patient reported outcome measures (PROMs) will be used to evaluate physical performance and satisfaction of subjects within 1 year after the index revision arthroplasty. A cost-utility analysis will only be performed when the primary outcome has demonstrated superiority of the extended regimen.

Study description

Background summary

Periprosthetic joint infection (PJI) is an important complication of total joint arthroplasty of the hip and knee and occurs in 1-2% after primary arthroplasty and in 10-15% after revision arthroplasty. To prevent a PJI,

peri-operative antibiotic prophylaxis is given. There*s inadequate evidence for a recommendation about the optimal duration of prophylaxis, especially in revision arthroplasty. The single dose prophylaxis follows the recommendation of the recent international guidelines and is therefore registered as control.

We hypothesize that the extended antibiotic prophylactic regimen is associated with increased infection-free survival of the implant within one year after revision arthroplasty (index revision arthroplasty) compared to a single dose.

Study objective

The aim of this multicenter open-label, randomized controlled trial is to investigate the superiority of 5 days (extended) versus a single dose of cefazolin prophylaxis in revision arthroplasty of the hip and knee.

Study design

This study is a multicenter open-label, randomized controlled superiority trial. Subjects will be randomized in a 1:1 ratio to the extended prophylaxis group and the single dose group (control). Randomization will be based on block randomization stratified by hospital of intervention (Radboudumc or SMK) and anatomic location of index revision arthroplasty (knee or hip). Subjects will be recruited at the orthopedic surgery departments of Radboudumc and SMK.

In this study subjects, orthopedic surgeons and investigators are not blinded. However, the evaluation of data for the primary outcome will be done by an Independent Data Review Committee (DRC), blinded for randomization.

Intervention

After obtaining informed consent, subjects will be randomized into 2 prophylactic groups:

A. Cefazolin at a single dose of 2 grams intravenously 15-60 minutes before incision, with a repeat dose of 2 grams if the duration of the procedure is more than 4 hours or when blood loss during the procedure is more than 1500ml.

B. Cefazolin at a dose of 2 grams intravenously 15-60 minutes before incision, with a repeat dose of 2 grams if the duration of the procedure is more than 4 hours or when blood loss during the procedure is more than 1500ml. This will be followed by cefazolin 1 gram intravenously t.i.d. until five days post-surgery. In case of impaired kidney function and obesity, dose adjustment will be performed.

Study burden and risks

- The proportion of SSI and PJI in both study groups during follow-up.
- The cefazolin susceptibility of the micro-organisms causing SSI and PJI in the study groups.
- The number of repeated surgeries.
- The reason for repeated surgery on the affected prosthetic joint during follow-up.
- Adverse drug events and serious adverse events.
- Risk factors associated with SSI and PJI.
- PROMs at weeks 12 and 52.

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

planned revision arthroplasty of the prosthesis of the hip or knee for

non-infectious reason

Exclusion criteria

periprosthetic joint infection on baseline

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2019
Enrollment:	780
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO

Date:	25-06-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	16-09-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-12-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-01-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-10-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	EUCTR2019-002438-35-NL
CCMO	NL70114.091.19