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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22317

Source
Nationaal Trial Register

Brief title
REViSION

Health condition

periprosthetic joint infection

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Junior Research Project (regional) University Medical Centre Radboudumc and Sint Maartenskliniek Nijmegen

Intervention

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

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

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 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 objective

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 design

study visits weeks 6, 12, 52.

Intervention

A) Cefazolin at a single dose of 2 grams intravenously 15-60 minutes before incision;

B) Cefazolin at a dose of 2 grams intravenously 15-60 minutes before incision, followed by cefazolin 1 gram intravenously t.i.d. until five days post-surgery.

S aureus dekolonisation

Contacts

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Eligibility criteria

Inclusion criteria

a. Aged 18 years or older.
b. Planned revision arthroplasty of the hip or knee prosthesis (index revision arthroplasty), with revision of one or more fixed components.

Exclusion criteria

a. If the index revision arthroplasty has been cancelled.
b. Revision of single mobile parts only.
c. PJI on baseline, based on ’definite infection’ score according to the Philadelphia consensus definition 2018
d. PJI on baseline, based on a positive culture of a single synovial fluid or tissue sample yielding a high virulence micro-organism (S. aureus, Enterobacterales, Pseudomonas spp, Acinetobacter spp, Candida spp).
e. Contraindication to cefazolin: previous allergic reaction, severe kidney disease defined as eGFR <10 ml/min.
f. Antimicrobial treatment within 3 days prior to index revision arthroplasty.
g. Subjects who are currently enrolled in investigational immunosuppressive drug trials.

h. Subjects who are unable to provide informed consent.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	02-09-2019
Enrollment:	780
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-06-2019
Application type:	First submission

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
NTR-new	NL7790
Other	CMO regio Arnhem - Nijmegen : 2019-5544

Study results