

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

NTR

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

Public

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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