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

Gepubliceerd: 08-06-2019 Laatst bijgewerkt: 18-08-2022

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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22317

Bron
Nationaal Trial Register

Verkorte titel
REViSION

Aandoening

periprosthetic joint infection

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Junior Research Project (regional) University Medical Centre Radboudumc and Sint Maartenskliniek Nijmegen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

study visits weeks 6, 12, 52.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

Radboudumc / Sint Maartenskliniek
Karin Veerman

0031683845606

Wetenschappelijk

Radboudumc / Sint Maartenskliniek
Karin Veerman

0031683845606

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-09-2019
Aantal proefpersonen:	780
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-06-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7790
Ander register	CMO regio Arnhem - Nijmegen : 2019-5544

Resultaten