Prophylactic Antibiotic Regimens in Tumor Surgery (PARITY): A Multi-Center Randomized Controlled Study Comparing Alternative Antibiotic Regimens in Patients Undergoing Tumor Resections with Endoprosthetic Replacements

Published: 21-07-2016
Last updated: 19-04-2024

The objective of this study is to determine whether long term (5 days) postoperative (cefazolin) antibiotics will decrease the rate of infection following lower extremity tumor surgery, when compared to short term (24 hours) postoperative (cefazolin...

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

Summary

ID

NL-OMON47195

Source
ToetsingOnline

Brief title
PARITY

Condition

- Bacterial infectious disorders
- Musculoskeletal and connective tissue neoplasms
- Bone and joint therapeutic procedures

Synonym
bone tumor, sarcoma

Research involving
Human

Sponsors and support

Primary sponsor: McMaster University
Source(s) of monetary or material Support: Orthopaedic Research & Education Foundation / Musculoskeletal Tumor Society (OREF/MSTS);Physician Services Incorporated (PSI) Canadian Cancer Society Research Institute (CCSRI)

Intervention

Keyword: bone tumor surgery, endoprosthetic reconstruction, infection, prophylactic antibiotic regimens

Outcome measures

Primary outcome

Development of a surgical site infection within 12 months following the initial surgical procedure.

Secondary outcome

Secondary objectives of this study are to determine the influence of the antibiotic regimen on the development of antibiotic-related complications (ie: gastrointestinal infections, fungal infections, etc.), functional outcomes and quality of life, the rate of re-operations, oncological recurrence and/or metastases , and mortality after one year.

Study description

Background summary

Endoprosthetic reconstruction after resection of a lower extremity bone tumor is associated with a high risk of infection. Infection of tumor prostheses can have detrimental consequences, ranging from the need to perform surgical debridement to amputation of the affected limb. Antibiotics are administered around the operation in an attempt to reduce the risk of infection. However, to

date, there is no consensus regarding the most effective antibiotic regimen.

Study objective

The objective of this study is to determine whether long term (5 days) postoperative (cefazolin) antibiotics will decrease the rate of infection following lower extremity tumor surgery, when compared to short term (24 hours) postoperative (cefazolin) antibiotics.

Study design

Multicenter, blinded, randomized controlled trial, using a parallel two-arm design.

Intervention

Long term (5 days) versus short term (24 hours) postoperative (cefazolin) antibiotics.

Study burden and risks

All visits and examinations are part of routine patient care. There are no additional risks associated with participation in this study other than possible complications associated with the routine patient care (the use of the approved and widely used antibiotics (cephalosporins)). A potential benefit of the long-term regimen is a reduction in the risk of postoperative infection. A potential risk of the long-term regimen is the development of side-effects and of bacterial resistance.

Contacts

Public
McMaster University

Wellington Street North 193
Hamilton L8L 8E7
CA
Scientific
McMaster University

Wellington Street North 193
Hamilton L8L 8E7
CA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1) Males and females 12 years of age or older;
2) Primary bone malignancies or benign aggres sive tumors of the femur or tibia, soft-tissue sarcomas which have
invaded the femur or tibia, or oligometastatic bone disease of the femur or tibia in a patient expected to live at
least one year post-operatively;
3) Treatment by excision and en doprosthetic reconstruction*;
4) Provision of informed consent

Exclusion criteria

1) Current known Methicillin-resistant Staphylococcus Aureus (MRSA), or Vancomycin Resistant Enterococcus (VRE) skin colonization*;
2) Documented anaphylaxis or angioedema to penicillin or the study antibiotics [cefazolin, or equivalent gram-positive coverage (i.e. cefuroxime)]
3) Prior surgery within the surgical field of the affected limb (excluding a biopsy);
4) Prior local infection within the surgical field of the limb**
5) Current known immunologically-deficient disease conditions (not including
recent chemotherapy) ***
6) Known renal insufficiency with estimated creatinine clearance (eGRF) of
less than 54 mL/min
7) Reconstruction to include allograft as well
8) Likely problems, in the judgement of the investigator, with maintaining
follow-up
9) Enrolled or previously randomized in a competing study

10)Patients who weigh less than or equal to 45kg

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-04-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	21-07-2016
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	11-09-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL54882.058.15