

# # 10624: Prophylactic Antibiotic Regimens in Tumor Surgery (PARITY): A pilot multi-center randomized controlled trial

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For the  
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## *Background*

Clinical studies of patients with bone sarcomas have been challenged by insufficient numbers at individual centers to draw valid conclusions. Our objective was to assess the feasibility of conducting a definitive large multi-center randomized controlled trial (RCT) by completing a pilot study.

## *Questions*

1. Is it feasible to conduct a multi-center RCT to determine whether a five-day regimen of post-operative antibiotics in comparison to a 24-hour regimen decreases the rate of surgical site infections (SSIs) in patients undergoing endoprosthetic reconstruction for lower extremity primary bone tumors?
2. What is the overall rate of SSIs in patients undergoing endoprosthetic reconstruction for lower extremity primary bone tumors?

## *Methods*

We performed a pilot international multi-center RCT. We used central randomization to conceal treatment allocation and sham antibiotics to blind participants, surgeons, and data collectors. We determined feasibility by measuring patient enrolment, completeness of follow-up, and protocol deviations for the antibiotic regimens. SSIs were diagnosed according to the definitions of the Centers for Disease Control and Prevention.

## *Results*

We screened 96 patients and enrolled 60 participants across 21 sites from 4 countries over 24 months (mean 2.13 participants per site per year, SD 2.14). One participant was lost to follow-up and one withdrew consent. Complete data were obtained for 98% of eligible patients at two weeks, 83% at six months, and 73% at one year (the remainder with partial data or pending queries). Eighteen participants missed at least one dose of antibiotics or placebo post-operatively, but 93% of all post-operative doses were administered per protocol. Nine participants (15%) experienced SSIs.

## *Conclusion*

It is feasible to conduct a definitive multi-center RCT of post-operative antibiotic regimens in patients with bone sarcomas, but further expansion of our collaborative network will be critical for definitive study completion. We have demonstrated an ability to coordinate this study in multiple countries, enrol participants, maintain high protocol adherence, and minimize losses to follow-up. This is the first study to confirm prospectively high SSI rates in tumor surgery.