

Δ A Pilot, Masked, Randomized Controlled Trial to Evaluate Local Gentamicin Versus Saline in Open Tibia Fractures

Billy Thomson Haonga, MD; Nae Yeon Won, BA, MPH; Ericka Von Kaeppler, BS; Claire Donnelley, BS; Edmund Ndalama Eliezer, MD, MMed; Mayur Urva, BS; Abigail Cortez, MD; Saam Morshed, MD; David Shearer, MD
Muhimbili Orthopaedic Institute, Dar es Salaam, Tanzania

Purpose: Open fractures have a high risk of infection with increased patient mortality, delayed healing, reoperation, and decreased functional outcome and quality of life. Antibiotics administered locally at the site of the open wound are a potentially effective preventive measure, but there are limited data evaluating aminoglycosides. The objective of this study is to assess the feasibility of a clinical trial aimed to test the efficacy of local gentamicin in reducing the risk of fracture-related infection (FRI) after open tibial fracture.

Methods: This study is a single-center pilot, masked, randomized controlled trial. All patients 18 years and older presenting to the emergency department with an open tibia fracture (Gustilo-Anderson types I, II, or IIIA; OTA Type 42) were eligible for this study. Patients were excluded if time from injury to presentation was >48 hours or time from injury to surgery was >7 days. Participants were randomized intraoperatively after wound closure to receive gentamicin solution (treatment) or normal saline solution (control) injected at the fracture site. Follow-ups were completed at 2 weeks, 6 weeks, 3 months, 6 months, 9 months, and 1 year postoperatively. The primary feasibility outcomes were the rate of enrollment and retention. The primary clinical outcome was the occurrence of FRI. Secondary outcomes measured were the occurrence of nonunion, unplanned fracture-related reoperations, EuroQol 5 Dimensions (EQ-5D) score, Function Index for Trauma (FIX-IT) score, and modified Radiographic Union Scale for Tibial Fractures (RUST) score.

Results: Of 199 patients screened, 100 eligible patients were successfully enrolled and randomized over 9 months (11.1 patients/mo). Most of the study population were male (80%) with an average age of 34 years (standard deviation 12.3). The primary mechanism was road traffic injury (85%). Complete data were recorded at baseline and follow-up for >95% of cases. The final rates of follow-up will be presented at the OTA Annual Meeting.

Conclusion: This pilot study is among the first to evaluate locally administered gentamicin in open tibial fractures. Results indicate a rigorous clinical trial with acceptable rates of enrollment and follow-up to address this topic is possible in this setting. We therefore plan to proceed with a well-powered definitive trial.

Δ OTA Grant

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device he or she wishes to use in clinical practice.