

Evaluation of a New Strategy for Protocolized Antibiotic Care for Severe Open Fractures: SEXTANT

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 64 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Injury meeting at least one of the following criteria: * Gustilo type III tibia (OTA 41 plateau, OTA 42 shaft and OTA 43 pilon) requiring a second procedure for final debridement and definitive coverage / closure following the index stabilization * Gustilo type IIIB ankle fractures (OTA 44) * Gustilo type IIIB calcaneus fractures (OTA 82) * Gustilo type IIIB talus fractures (OTA 81) * Traumatic "zone-of-injury" trans-tibial amputations requiring DPC, and/or flap coverage 2. Ages 18 •64 years inclusive 3. Patients may have risk factors for infection including diabetes, immunosuppression from steroids or other medications, HIV, or other infections. 4. Patients may have a traumatic brain injury. 5. Patients may have other fractures including spine, upper extremity fractures, contralateral lower extremity injuries, ipsilateral pelvis, hip, femur or foot injuries. 6. Patients may be treated initially at an outside institution prior to transfer to the study institution, as long as the definitive wound closure or coverage was not performed prior to entrance into the study. 7. Patients with bilateral injuries that meet inclusion criteria may be included, but only the limb rated as "more severe" by the treating surgeon will be enrolled in the study. 8. Patients may have co-existing non-tibial or hindfoot infection, with or without antibiotic treatment. 9. Patients may be definitively stabilized using any method (nail, plate, ex fix or cast). 10. Patients may have a fasciotomy.

Exclusion Criteria:

1. Patient in current therapy for a wound, implant or fracture site infection related to the study site. 2. Patient likely to have difficulty maintaining follow-up, including: * Diagnosis of a severe psychiatric condition * Intellectually challenged without adequate family support * Resides outside of the hospital's catchment area * Planning to follow-up at another medical center * Being a prisoner * Not having a means of contact (address, cell phone, home phone, e-mail)

Conditions & Interventions

Interventions:

DRUG: Standard of care, DRUG: Vancomycin and Tobramycin

Conditions:

Post Operative Surgical Site Infection

Keywords:

Surgical site infection risk prevention, Bacterial species type and antibacterial sensitivities

More Information

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Phase: PHASE3

IRB

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