

Antibiotic Cement Bead Pouch Versus Negative Pressure Wound Therapy

NCT05615844

Status	RECRUITING
Phase	Phase 3
Sponsor	University of Maryland, Baltimore
Enrollment	312 participants

Key Eligibility Criteria

Inclusion (6)

- Patients 18 years of age or older.
- Severe open tibia fracture requiring more than one irrigation and debridement procedure to treat the open fracture.
- Planned internal or external fixation for definitive fracture management.
- Formal surgical debridement within 72 hours of their injury.
- Will have all planned fracture care surgeries performed by a participating surgeon or delegate.

... and 1 more (see full listing online)

Exclusion (12)

- Due to the severity of injury, the treating surgeon does not believe limb salvage >6 months is likely to be successful based on the emergency department or initial intraoperative assessment (prior to enrolment and randomization).
- Medical contraindication to antibiotic beads, including previously known allergies or sensitivities to vancomycin and/or tobramycin.
- Medical or injury contraindication to NPWT. Injury contraindications could include situations in which the NPWT could not be placed over a vascular graft or exposed neurovascular structure.
- Received previous surgical debridement or management of their fracture at a non-participating hospital or clinic (as applicable).
- Chronic or acute infection at or near the fracture site at the time of initial fracture surgery.

... and 7 more (see full listing online)

Locations (33 total)

Dignity Health Chandler Regional Medical Center, Chandler, Arizona, United States
University of California, Davis, Davis, California, United States
University of Southern California, Los Angeles, California, United States
... and 30 more locations