

Multicenter Trial of Antibiotic Eluting Graft for Promoting New Bone Growth In/near Infected Bone Cavities

NCT05361941

Status	RECRUITING
Phase	Not Applicable
Sponsor	Elute, Inc.
Enrollment	204 participants

Key Eligibility Criteria

Inclusion (6)

- Ages and sexes eligible: at least 22 years, male and female
- Candidates with known infected TKA
- Life expectancy of at least 1 year
- Patient is willing to provide informed consent, is geographically stable and able to comply with the required follow up visits, testing schedule and medication regimen
- Adequate soft tissue coverage
- ... and 1 more (see full listing online)

Exclusion (11)

- Severe renal impairment with eGFR ≤ 50 ml/min/1.73 m², or being treated with dialysis
- Known hypersensitivity to aminoglycoside antibiotics, or calcium hydroxyapatite
- Pre-existing calcium metabolism disorder
- Uncontrolled diabetes mellitus (hemoglobin A1c levels ≥ 8)
- A current endocrine or metabolic disorder known to affect osteogenesis (e.g., Paget's disease, renal osteodystrophy, hyperthyroid parathyroid hormone disorder, Ehler-Danlos syndrome, osteogenesis imperfecta)
- ... and 6 more (see full listing online)

Locations (12 total)

University of Southern California, Los Angeles, California, United States
Endeavor Health Skokie Hospital, Skokie, Illinois, United States
OrthoIndy, Indianapolis, Indiana, United States
... and 9 more locations

<https://clinicaltrials.gov/study/NCT05361941>

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