A Phase 1/2 Study to Evaluate the Safety, PK and Efficacy of TNP-2092 Administered Via IA Injection in PJI Participants

NCT06889701

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	TenNor Therapeutics Inc.
Enrollment	33 participants

Key Eligibility Criteria

Inclusion (8)

- Early (within 1 month of TKA) or acute hematogenous (within 3 weeks of infectious symptoms) PJI requires or does not require DAIR therapy after TKA, or results of treatment for PJI (including PJI occurring after various joint replacements and revision surgeries) did not meet the clinical cure criteria and requiring long-term antibiotic suppression therapy as judged by investigators before enrollment.
- Suspected or confirmed PJI was caused by a Gram-positive bacterial infection, including methicillin-resistant and ciprofloxacin-resistant Staphylococcus aureus and Staphylococcus epidermidis, as judged by the investigator.
- Agree to be hospitalized for 2 weeks with local intra-articular injection.
- years of age or older (of either sex) at the time of signing the informed consent form (ICF).
- The implanted prosthetic joint was well fixed.

... and 3 more (see full listing online)

Exclusion (16)

- History of hypersensitivity or intolerance to any of the following agents: vancomycin or TNP-2092.
- Definite PJI of Gram-negative infection, fungal infection, or Enterococcus infection, or Mycobacterium infection, or Gram-positive mixed Gram-negative and/or fungal infection.
- Definite systemic infection (sepsis).
- Expected survival less than 1 years.
- Female participant is pregnant, lactating, or has a positive screening/baseline pregnancy test.

... and 11 more (see full listing online)

Locations (1 total)

The First Affiliated Hospital of Xinjiang Medical University, Ürümqi, Xinjiang, China