

Program for Rifampicin-Resistant Disease With Stratified Medicine for Tuberculosis

NCT06441006

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	University of California, San Francisco
Enrollment	400 participants

Key Eligibility Criteria

Inclusion (11)

- Confirmed fluoroquinolone-susceptible rifampicin-resistant pulmonary tuberculosis, based on sputum Xpert MTB/RIF and Xpert MTB/XDR, and/or other validated molecular test, and/or phenotypic drug susceptibility testing.
- a. NOTE: TB diagnosis for purposes of meeting this inclusion criterion can be from a study testing laboratory or from an outside laboratory.
- Aged e 14 years.
- A verifiable address or residence location that is readily available for visiting, willingness to consent to home visits and phone calls, and willingness to inform the study team of any change of address during the treatment and follow-up period.
- Ability and willingness of individual to provide written informed consent or written consent from a parent, guardian, or caregiver and assent of the child participant per local ethics committee guidance.

... and 6 more (see full listing online)

Exclusion (24)

- Known allergy/sensitivity, intolerance, or any hypersensitivity to components of study TB drugs or their formulation.
- One or more of the following laboratory parameters:
- Absolute neutrophil count (ANC) \lt 1000/mm³.
- Hemoglobin level \lt 8.0 g/dL.
- Serum or plasma alanine aminotransferase (ALT) or aspartate aminotransferase (AST) e 3 times the upper limit of normal.

... and 19 more (see full listing online)

Locations (6 total)

National Center for Communicable Diseases, Ulaanbaatar, Mongolia
Institute of Chest Diseases, Kotri, Pakistan
Hospital Nacional Sergio E. Bernales, Lima, Peru

... and 3 more locations