Efficacy and Tolerability of Bedaquiline, Delamanid, Levofloxacin, Linezolid, and Clofazimine to Treat MDR-TB

NCT03828201

Status	RECRUITING
Phase	Phase 2
Sponsor	Boston University
Enrollment	220 participants

Key Eligibility Criteria

Inclusion (6)

- Males and females age e12 years. Prior to study procedures, if e18 years of age, provides informed consent; if \<18 years of age, child provides informed assent and has a parent or guardian who provides informed consent on the participant's behalf.
- Has pulmonary TB based on investigator assessment of all available information (e.g., chest radiograph, sputum smear, culture, molecular testing).
- Has a sputum sample that is positive for M. tuberculosis that is rifamycin-resistant and fluoroquinolone-susceptible by molecular assay.
- Is HIV seropositive or seronegative; HIV serostatus must be assessed at screening if either (a) HIV serostatus is unknown, or (b) the last documented negative HIV test was more than two (2) months prior to screening.
- Willing to attend scheduled follow-up visits and undergo study assessments.

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

Exclusion (24)

- Current MTB isolate is known at screening to be fluoroquinolone-resistant.
- History of allergy (hypersensitivity) or intolerability to one or more agents in the investigational regimens (i.e., Arms 1 and 2)
- History of serotonin syndrome
- History of symptomatic ventricular arrhythmia or is taking anti-arrhythmic agents
- History of optic neuropathy or peripheral neuropathy

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

Locations (2 total)

De La Salle Health Sciences Institute, Dasmariñas, Philippines
National Lung Hospital, Hanoi, Vietnam