

Study of a Single Dose of Pretomanid Added to an Optimized Background Regimen in Children With Rifampicin-Resistant Tuberculosis

NCT05586230

Status	RECRUITING
Phase	Phase 1
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	72 participants

Key Eligibility Criteria

Inclusion (46)

- If not of legal age or circumstance to provide independent informed consent as determined by site standard operating procedures (SOPs) and consistent with institutional review board/ethics committee (IRB/EC) policies and procedures: Parent/legal guardian is willing and able to provide written informed consent for potential participant's study participation; in addition, when applicable per IRB/EC policies and procedures, potential participant is willing and able to provide written assent for study participation.
 - If of legal age or circumstance to provide independent informed consent as determined by site SOPs and consistent with IRB/EC policies and procedures: Potential participant is willing and able to provide written informed consent for study participation.
 - Note: All sites must follow all applicable IRB/EC policies and procedures.
 - Assigned female sex at birth, as determined by the site investigator based on participant and parent/guardian report and available medical records
 - Age less than 18 years of age at entry
- ... and 41 more (see full listing online)

Exclusion (16)

- Has tuberculosis meningitis Stage 2 or 3, as determined by the site investigator based on medical records
 - Receipt of any of the following, within 14 days prior to entry, as determined by the site investigator based on participant/parent/guardian report and available medical records
 - Rifamycins
 - Any prohibited medication (see protocol for listing)
 - For participants living with HIV: ritonavir-boosted protease inhibitors (e.g., ritonavir-boosted lopinavir, ritonavir-boosted darunavir), atazanavir, nevirapine etravirine, efavirenz, or cobicistat
- ... and 11 more (see full listing online)

Locations (6 total)

Site 5071, Instituto de Puericultura e Pediatria Martagao Gesteira CRS, Rio de Janeiro, Brazil
Site 31441, BJMC CRS, Pune, India
Site 31976, PHRU Matlosana CRS, Klerksdorp, North West, South Africa
... and 3 more locations