

Shortened Regimen for Drug-susceptible TB in Children

NCT06253715

Status	RECRUITING
Phase	Phase 3
Sponsor	Johns Hopkins University
Enrollment	860 participants

Key Eligibility Criteria

Inclusion (23)

- Parent or guardian is willing and able to provide written informed consent for potential participant's study participation; in addition, when applicable per Ethics Committee/Institutional Review Board (EC/IRB) policies and procedures, potential participant is willing and able to provide assent for study participation.
 - At Entry, age of less than 10 years.
 - At Entry, weight 3 kilograms (kg) or greater.
 - At Entry, diagnosed with TB disease, defined as:
 - Pulmonary (including pleural effusion) and/or lymph node (extra-thoracic and/or intra-thoracic) TB with or without bacteriologic confirmation;
- ... and 18 more (see full listing online)

Exclusion (15)

- Presumed or documented extra-pulmonary TB involving the central nervous system and/or bones and/or joints, and/or miliary TB, and/or pericardial TB and/or TB of the gastrointestinal (GI) tract and/or renal TB.
 - Premature infant (born less than 37-weeks gestation) who is less than 3 months of age at Entry.
 - Any known contraindication to taking any study drug:
 - Known allergy or intolerance to any of the study drugs or drugs in the same class as the study drugs;
 - Any prohibited medications within three days prior to Entry or planned use within the following 6 months;
- ... and 10 more (see full listing online)

Locations (9 total)

Indian Council of Medical Research - National Institute for Research in Tuberculosis, Chennai, India
Dr. D.Y. Patil Medical College, Hospital and Research Center, Pune, India
Faculty of Medicine, Universitas Padjadjaran, Bandung, Indonesia
... and 6 more locations

<https://clinicaltrials.gov/study/NCT06253715>

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