RESIST-TB

Research Excellence to Stop TB Resistance

DRUG-RESISTANT TUBERCULOSIS CLINICAL TRIALS PROGRESS REPORT

Trial Name	Description	Status	Phase	Trial Registry Identifier (link)	Expected Study Completion Date
Janssen C211	Evaluate the PK, safety, tolerability and anti-mycobacterial activity of bedaquiline in combination with MDR-TB therapy for HIV uninfected children and adolescents	Currently enrolling in Philippines, Russian Federation, and South Africa	Phase 2	NCT02354014	2025
STREAM Stage 1	Comparison of standard WHO MDR-TB regimen with 9-month modified Bangladesh Regimen	Completed; results	Phase 3	ISRCTN78372190	Completed
STREAM Stage 2	Comparison of 6 and 9 month bedaquiline-containing regimen against the WHO and Bangladesh regimen	Open for participant enrollment	Phase 3	NCT02409290	2021
NeXT	Open label RCT of a 6-9 month injection free regimen containing bedaquiline, linezolid, levofloxacin, ethionamide/high dose isoniazid, and pyrazinamide	Enrollment suspended	Phase 3	NCT02454205 PACTR201409000848428	2019
NiX-TB	Study of bedaquiline, pretomanid, and linezolid in patients with XDR-TB and MDR-TB for 6 months with an option of 9 months	Completed; results	Phase 3	NCT02333799	Completed
DELIBERATE (ACTG 5343)	Study of drug-drug interactions and combined QT effects of bedaquiline and delamanid	Fully enrolled Preliminary results	Phase 2	NCT02583048	2020
Otsuka 213	Safety and efficacy study of delamanid or placebo for 6 months in combination with optimized background therapy for 18-24 months	Completed results here.	Phase 3	NCT01424670	2018
Otsuka 233	Safety, efficacy, and pharmacokinetic study of delamanid in pediatric patients with MDR-TB	Fully enrolled.	Phase 2	NCT01859923	2020
Otsuka 232	Pharmacokinetic and safety trial of delamanid to determine the appropriate dose for pediatric MDR-TB HIV- patients	Completed; results pending	Phase 1	NCT01856634	2019
ACTG 5312	Safety and efficacy study of different doses and generic variants of isoniazid resistant TB	Stage 1 preliminary results; Stage 2 underway	Phase 2	NCT01936831	2019

RESIST-TB

Research Excellence to Stop TB Resistance

DRUG-RESISTANT TUBERCULOSIS CLINICAL TRIALS PROGRESS REPORT

Trial Name	Description	Status	Phase	Trial Registry Identifier (link)	Expected Study Completion Date
Opti-Q	Efficacy and safety study of increased doses of levofloxacin in combination with optimized background therapy	Follow up completed; anaylsis underway	Phase 2	NCT01918397	2019
V-QUIN	Evaluating 6 months daily levofloxacin vs. placebo as preventive therapy in contacts of MDR-TB. Enrolling Children, adolescents, infants HIV+/HIV- Household randomization	Currently enrolling participants in Vietnam	Phase 3	ACTRN12616000215426	2019
MDR-END	Comparing efficacy of treatment regimen including delamanid, linezolid, levofloxacin, and pyrazinamide for 9-12 months, with a control arm of the standard treatment regimen including injectables for 20-24 months for the treatment of quinolone sensitive MDR-TB	Currently enrolling participants in South Korea	Phase 2	NCT02619994	2021
TB-CHAMP	Randomized double blind placebo-controlled, superiority multicenter trial to evaluate the efficacy of levofloxacin vs. placebo for the prevention of MDR-TB in child and adolescent household contacts	Currently enrolling participants in South Africa	Phase 3	ISRCTN92634082	2020
Janssen Japan Trial	Open-label, single-arm, multi-center trial to explore safety, efficacy and PK of bedaquiline in Japanese participants with pulmonary MDR-TB	Completed Results	Phase 2	NCT02365623	Completed
endTB	Phase III, randomized, controlled, open-label, non-inferiority, multi-country trial evaluating the efficacy and safety of new combination regimens for FQ-susceptible MDR-TB treatment	Currently enrolling participants in Georgia, Peru, Kazakhstan, and Lesotho	Phase 3	NCT02754765	2022
TB-PRACTECAL	Multi-centre, open label, multi-arm, randomized, controlled, phase II-III trial evaluating short treatment regimens containing bedaquiline and pretomanid in combination with existing and re-purposed anti-TB drugs for the treatment of biologically confirmed pulmonary MDR-TB	Currently enrolling participants in Uzbekistan, South Africa, and Belarus	Phase 2-3	NCT02589782	2022
ZeNix	Evaluate the efficacy, safety and tolerability of various doses and durations of linezolid plus bedaquiline and pretomanid after 26 weeks of treatment in participants with either pulmonary XDR-TB, pre-XDR-TB, or treatment intolerant or non-responsive MDR-TB.	Currently enrolling participants in Georgia, Republic of Moldova, Russian Federation, South Africa	Phase 3	NCT03086486	2020

RESIST-TB

Research Excellence to Stop TB Resistance

DRUG-RESISTANT TUBERCULOSIS
CLINICAL TRIALS PROGRESS REPORT

Trial Name	Description	Status	Phase	Trial Registry Identifier (link)	Expected Study Completion Date
SimpliciTB	DR-TB pateints given BPaMZ for 26 weeks (or 6 months).	Currently enrolling patients	Phase 2-3	NCT03338621	2022
IMPAACT 2005 (DAIDS ID 20721)	The purpose of this study is to evaluate the pharmacokinetics, safety and tolerability of Delmanid in combination with optimized multidrug background regimen (OBR) for multidrug-resistant tuberculosis (MDR-TB) in HIV-infected and HIV-uninfected children with MDR-TB	Currently enrolling participants in Botswana, India, South Africa and Tanzania	Phase 1-2	NCT03338621	2021
IMPAACT 2005 (DAIDS ID 11884)	The purpose of this study is to evaluate the pharmacokinetics (PK), safety, and tolerability of an antituberculosis drug, bedaquiline (BDQ), when used to treat multidrug-resistant tuberculosis (MDR-TB) in HIV-infected and HIV-uninfected infants, children, and adolescents.	Currently enrolling non-US participants in Haiti, India and South Africa	Phase 1-2	NCT03141060	2022
BEAT-TB	Building Evidence for Advancing New Treatment for Rifampicin Resistant Tuberculosis (RR-TB) Comparing a Short Course of Treatment (Containing Bedaquiline, Delamanid and Linezolid) With the Current South African Standard of Care	Currently open for enrollment in South Africa	Phase 3	NCT04062201	2023