A Phase III Study of Oral Sudapyridine (WX-081) Tablets in Rifampicin-Resistant Pulmonary Tuberculosis Patients

NCT05824871

Status	RECRUITING
Phase	Phase 3
Sponsor	Shanghai Jiatan Pharmatech Co., Ltd
Enrollment	450 participants

Key Eligibility Criteria

Inclusion (5)

- • Body mass index (BMI) and body weight of subjects: 15.0dBMId28.0 kg/m2, and 40kgd body weight d90kg;
- For clinically diagnosed patients with tuberculosis whose drug sensitivity test has proved to be at least resistant to rifampicin, phenotypic or molecular drug sensitivity test results within 3 months before the subject signs informed consent can be accepted;
- Direct sputum smear positive for acid-fast bacilli (AFB at least 1+);
- Willing to discontinue all previous anti-tuberculosis drugs and accept a 7-day washout period;
- Non-lactating and pregnant women who agree to use contraception throughout the treatment; Or the male patient's spouse agrees to use contraception throughout the treatment.

Exclusion (12)

- • Allergic to any study drug or its ingredients;
- A history of alcohol dependence or drug abuse;
- With hematogenous disseminated pulmonary tuberculosis or extrapulmonary tuberculosis;
- Drug susceptibility test before screening showed resistance to more than 4 of the 8 antituberculosis drugs in this study;
- Have taken Bedaquiline before;

... and 7 more (see full listing online)

Locations (2 total)

Beijing Chest Hospital affiliated to Capital Medical University, Beijing, Beijing Municipality, China
Beijing Chest Hospital, Capital Medical University, Beijing, Beijing Municipality, China