A Adaptive Design Clinical Trial to Evaluate the Efficacy and Safety of TDI01 Suspension in the Treatment of Idiopathic Pulmonary Fibrosis (IPF)

NCT07464912

Status	RECRUITING
Phase	Phase 3
Sponsor	Beijing Tide Pharmaceutical Co., Ltd
Enrollment	508 participants

Key Eligibility Criteria

Inclusion (29)

- Diagnosed with IPF
- Confirmed diagnosis before screening: Diagnosis was made according to the 2022 clinical practice guideline principles of the American Thoracic Society (ATS), European Respiratory Society (ERS), Japanese Respiratory Society (JRS), and Latin American Thoracic Society (ALAT) (see Appendix 1), confirmed by the investigators based on chest high-resolution CT (HRCT) performed within 12 months before Visit 1, and surgical lung biopsy or transbronchial lung cryobiopsy (if available);
- Reconfirmation of IPF diagnosis at screening: And before Visit 2, the independent imaging review panel of experts reviewed and confirmed that the HRCT (HRCT within 3 months before randomisation in the same site was accepted) is consistent with a clinical diagnosis of usual interstitial pneumonia (UIP) or probable UIP for IPF. For subjects with an HRCT finding of "indeterminate for UIP", if a local (previous) surgical lung biopsy or transbronchial lung cryobiopsy has been performed, the pathological slides must be submitted for central review and assessment. If the histopathological features show "UIP" or "probable UIP", the clinical diagnosis of IPF can be confirmed;
- Voluntarily participates in this clinical study and signs the informed consent form before the start of the study;
- Age is 40-80 years (inclusive of 40 and 80 years) at the time of signing the informed consent form, regardless of sex;

... and 24 more (see full listing online)

Exclusion (34)

- Subjects who meet any of the following criteria will not be allowed to participate in this study:
- Other known causes of interstitial lung disease, such as home or occupational environmental exposure, connective tissue disease, drugs, etc.;
- With other clinically significant lung diseases besides IPF (such as asthma, COPD or significant airways obstruction \[FEV1/FVC ratio \<0.7\], hypersensitivity pneumonitis, eosinophilic pneumonia, etc.);
- Patients who are planning to undergo a lung transplant within 12 months after screening;
- Active infection tuberculosis within 12 months prior to screening, or any active bacterial, viral, parasitic, or fungal infection requiring systemic treatment during the screening period;

... and 29 more (see full listing online)

Locations (1 total)

China-Japan Friendship Hospital, Beijing, Beijing Municipality, China