

Anlotinib Capsules in the Treatment for IPF/PF-ILDs

NCT05828953

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	First Affiliated Hospital of Wenzhou Medical University
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (10)

- The participants voluntarily joined the study and signed an informed consent form. They showed good compliance throughout the study.
- The study includes individuals aged 40-85 years old, of any gender, with an expected lifespan of over 1 year.
- Subjects who meet either of the following two criteria: a. HRCT results confirming IPF diagnosis within the past 5 years and HRCT results within the past 12 months showing a range of parenchymal fibrotic changes between $\geq 10\%$ and $< 50\%$, with less than 25% honeycombing change in the lung, and no other facilitating factors (e.g. asbestos exposure, allergic pneumonia, systemic sclerosis, rheumatoid arthritis) as detailed in Annex 1A. b. PF-ILDs: Patients with characteristics of fibrotic lung disease (see Annex 1B), and at least one of the following diagnostic criteria is met: i. Relative decline in FVC% predicted by $\geq 10\%$ within 6 months; ii. Relative decline in FVC% predicted by $\geq 5-10\%$ with worsening respiratory symptoms, or an increase in the degree of fibrosis on chest HRCT; iii. Worsening respiratory symptoms combined with an increase in the degree of fibrosis on chest HRCT;
- Carbon monoxide diffusion capacity (DLco) (corrected for hemoglobin) between 30% and 80% of predicted value;
- Force vital capacity (FVC) $\geq 45\%$ predicted;
- ... and 5 more (see full listing online)

Exclusion (20)

- Patients with acute exacerbation of PF/PF-ILDs.;
- Multiple factors that affect oral medication (such as dysphagia, chronic diarrhea, and intestinal obstruction)
- Received major surgical treatment, incisional biopsy, or significant traumatic injury within 28 days prior to the start of the study treatment.
- Long-standing non-healing wound or fracture.
- Patients who have experienced thrombotic events, such as cerebrovascular accidents (including transient ischemic attacks, cerebral hemorrhage, and cerebral infarction), deep vein thrombosis, and pulmonary embolism, within the past 6 months, or those with other bleeding tendencies.
- ... and 15 more (see full listing online)

Locations (1 total)

The First Affiliated Hospital of Wenzhou Medical University, Wenzhou, Zhejiang, China

<https://clinicaltrials.gov/study/NCT05828953>

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