A Randomized, Double-blind, Placebo-controlled Phase II Clinical Study to Evaluate the Safety, Tolerability, Efficacy, and Pharmaco-kinetic Profile of Genakumab Injection in Patients With Connective Tissue Disease-associated Interstitial Lung Disease

NCT06189495

Status	RECRUITING
Phase	Phase 2
Sponsor	Changchun GeneScience Pharmaceutical Co., Ltd.
Enrollment	30 participants

Plain Language Summary

This Phase II study tests genakumab — a new injectable drug — in people with connective tissue disease (such as rheumatoid arthritis or systemic sclerosis) who have also developed interstitial lung disease (ILD), a condition where scar tissue builds up in the lungs and makes breathing difficult.

You may be eligible if...
- You are between 18 and 75 years old
- You have been diagnosed with rheumatoid arthritis (RA) or systemic sclerosis (SSc) using established medical criteria
- You also have interstitial lung disease confirmed by a high-resolution CT scan of your chest
- Your lung function has declined over time and you have moderate to severe lung involvement

You may NOT be eligible if...
- Your ILD is caused by something other than RA or systemic sclerosis
- You have another serious lung condition (such as COPD or active tuberculosis)
- You are pregnant or breastfeeding
- You have a serious infection or immune system disorder

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (8)

- Those who voluntarily sign informed consent and can complete the experiment according to the plan;
- Age 18-75 years old (including upper and lower limits), both male and female;
- Rheumatoid arthritis (RA) diagnosed according to the 2010 American College of Rheumatology (ACR)/European League against Rheumatism (EULAR) classification, or Systemic sclerosis (SSc) according to the 2013 ACR/EULAR classification;
- Interstitial lung disease (ILD) was confirmed by HRCT within 12 months before screening.
- FVCe 40% of the expected value during the screening period;

... and 3 more (see full listing online)

Exclusion (36)

- Allergic to experimental drugs or biological agents; People who have previously known other severe allergic reactions;
- Airway obstruction (FEV1/FVC\<0.7 before bronchodilator use) or other lung abnormalities deemed clinically significant by the investigator or a history of asthma;
- Those who have received any of the following drugs or treatments :
- Receiving prednisone \>15mg/ day or equivalent dose of glucocorticoid within 2 weeks prior to randomization;
- Receive azathioprine, colchicine, D-penicillamine, sulfasalazine within 8 weeks before randomization;

... and 31 more (see full listing online)

Locations (4 total)

Peking University Third Hospital, Beijing, Beijing Municipality, China
Union Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology, Wuhan, Hubei, China
Qilu Hospital of Shandong University, Jinan, Shandong, China
... and 1 more locations