

A Study to Test Whether Nerandomilast Helps People With Lungfibrosis Related to Rheumatic Diseases

NCT06806592

Status	RECRUITING
Phase	Phase 3
Sponsor	Boehringer Ingelheim
Enrollment	400 participants

Key Eligibility Criteria

Inclusion (13)

- Participant has systemic autoimmune rheumatic diseases associated interstitial lung diseases (SARD-ILD), defined as
- Diagnosis by a rheumatologist with at least 1 of the following SARDs: Rheumatoid arthritis (RA), systemic sclerosis (SSc) (participants must be anticentromere auto-antibody negative), idiopathic inflammatory myopathy (IIM), Sjögren's disease, or Mixed connective tissue disease (MCTD)
- Presence of fibrotic interstitial lung disease (ILD) on high-resolution computed tomography (HRCT), defined as presence of reticular abnormality with traction bronchiectasis with or without honeycombing (HC), with disease extent $\geq 10\%$ on HRCT performed within 12 months of Visit 1 or, if historical scan is not available, on baseline HRCT taken prior to Visit 2, as confirmed by central review
- No lung function improvement and no clinically significant ILD improvement as a treatment response to immunosuppressant (IS) therapy according to both criteria:
- No improvement in absolute forced vital capacity (FVC) % predicted $\geq 5\%$ within the 15 months prior to Visit 1, as measured by 2 spirometry assessments that must be ≥ 3 months apart. (Note: Visit 1 spirometry may be used to fulfill the inclusion criterion if there is only 1 spirometry reading in the 15 months prior to Visit 1)

... and 8 more (see full listing online)

Exclusion (7)

- Organising pneumonia as predominant pattern in the HRCT
- Prebronchodilator forced expiratory volume in 1 second (FEV1)/ forced vital capacity (FVC) < 0.7 at Visit 1
- Acute ILD exacerbation within 3 months prior to Visit 1 and/or during the screening period, based on Investigator judgement
- Active vasculitis, unstable or uncontrolled within 8 weeks prior to Visit 1 or during the screening period
- Any suicidal behaviour in the past 2 years

... and 2 more (see full listing online)

Locations (158 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States

Mayo Clinic-Arizona, Scottsdale, Arizona, United States

University of California Los Angeles, Los Angeles, California, United States

... and 155 more locations

<https://clinicaltrials.gov/study/NCT06806592>

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