

# Platform Clinical Study for Conquering Scleroderma

NCT06195072

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 2
<b>Sponsor</b>	Scleroderma Research Foundation, Inc.
<b>Enrollment</b>	400 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Male or female 18+ years of age at the time of signed informed consent;
  - SSc classification as defined by the 2013 American College of Rheumatology/European League Against Rheumatism criteria. Participants with diffuse, limited or sine cutaneous skin involvement are eligible
  - Onset of SSc (defined by first non-Raynaud's symptom) 7 years or less prior to the Screening Visit;
  - A Modified Rodnan skin score (mRSS) less than 40
  - Presence of ILD with evidence of any fibrosis on HRCT (within 3 months or less of randomization)
- ... and 2 more (see full listing online)

### Exclusion (20)

- Presence of clinically significant pulmonary abnormalities inconsistent with ILD on HRCT (e.g., scarring due to previous active tuberculosis [TB], sarcoidosis, lung mass, or other findings unrelated to SSc-ILD, as determined by a local radiologist/Investigator);
  - Presence of infected ulcers or active gangrene at the Screening Visit;
  - History of scleroderma renal crisis within 6 months prior to the Screening Visit;
  - Forced expiratory volume in 1 second/FVC  $<0.65$  (pre-bronchodilator) at the Screening Visit
  - History of stem cell transplantation, bone marrow transplantation, chimeric antigen receptor T-cell therapy, or solid organ transplantation;
- ... and 15 more (see full listing online)

## Locations (34 total)

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University of Alabama - Division of Pulmonary and Critical Care Medicine, Birmingham, Alabama, United States  
Keck School of Medicine at USC Medical Center, Los Angeles, California, United States  
Cedars-Sinai Medical Center, Los Angeles, California, United States  
... and 31 more locations

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<https://clinicaltrials.gov/study/NCT06195072>

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