

A Study of Nemolizumab for the Treatment of Adults With Systemic Sclerosis

NCT07047690

Status	RECRUITING
Phase	Phase 2
Sponsor	Galderma R&D
Enrollment	162 participants

Key Eligibility Criteria

Inclusion (15)

- Participant must be 18 years of age or older, at the time of signing the Informed Consent Form.
- Classification of systemic sclerosis (SSc) as defined by the 2013 American College of Rheumatology [ACR]/European League Against Rheumatism [EULAR] criteria.
- Modified Rodnan Skin Score.
- Diffuse cutaneous systemic sclerosis (DcSSc) participants and modified Rodnan Skin Score (mRSS) of greater than equal to (\geq)12 and less than ($<$)30 at both screening and baseline
- Limited cutaneous systemic sclerosis (LcSSc) participants with mRSS \geq 8 at both screening and baseline. LcSSc participants with positive anti-centromere at screening are excluded.

... and 10 more (see full listing online)

Exclusion (26)

- Anti-centromere antibody positive at screening for participants with LcSSc.
- Anti-RNA polymerase 3 antibody positive for participants with a disease duration $>$ 18months.
- Creatinine clearance $<$ 30 milli liter per minute [ml/min] (calculated by Cockcroft-Gault formula).
- Positive serology results (hepatitis B surface antigen [HBsAg] or hepatitis B core antibody [HbcAb], hepatitis C [HCV] antibody with positive confirmatory test for hepatitis C virus [HCV] antibody with positive HCV RNA, or human immunodeficiency virus [HIV] antibody).
- FVC $<$ 50% of predicted normal value, and DLCO $<$ 40% of predicted normal value (corrected for Hb) at screening and baseline.

... and 21 more (see full listing online)

Locations (3 total)

Galderma Investigational Site # 8743, Ann Arbor, Michigan, United States
Galderma Investigational Site#7096, Arlington, Texas, United States
Galderma Investigational Site # 6213, Sankt Gallen, Switzerland

<https://clinicaltrials.gov/study/NCT07047690>

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