

Nebulized Human Amniotic Fluid in Patients With Interstitial Lung Disease

NCT07372989

Status	RECRUITING
Phase	Phase 1
Sponsor	Maule Stem Cell Research Institute, Inc.
Enrollment	50 participants

Key Eligibility Criteria

Inclusion (8)

- In order to participate in this study, a patient MUST:
- Provide written informed consent.
- Subjects age ≥ 40 and < 90 years at the time of signing the Informed Consent Form.
- Have a clinical diagnosis of ILD prior to screening in accordance with the guidelines of the American Thoracic Society/European Respiratory Society.
- FVC $\geq 45\%$ predicted and DLCO $\geq 30\%$ (corrected for hemoglobin but not alveolar volume).
- ... and 3 more (see full listing online)

Exclusion (18)

- In order to participate in this study, a patient MUST NOT:
- CT and/or surgical lung biopsy results inconsistent with the diagnosis of IPF.
- Inability to perform any of the assessments required for endpoint analysis (report safety or tolerability concerns, perform PFTs or CT, undergo blood draws, read and respond to questionnaires.)
- Currently receiving (or received within four weeks of screening) any medication, treatment, or experimental agents for the treatment of ILD, except for patients receiving non-drug therapies will include oxygen saturation therapy (oxygen supplementation) and pulmonary rehabilitation.
- Active listing (or expected future listing) for transplant of any organ.
- ... and 13 more (see full listing online)

Locations (1 total)

Maule Stem Cell Research Institute, Venice, Florida, United States