Clinical Trial Details (PDF Generation Date :- Sun, 27 Nov 2022 11:45:25 GMT)

CTRI Number	CTRI/2018/01/011449 [Registered on: 19/01/2018] - **Trial Registered Prospectively**
Last Modified On	12/11/2018
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Drug
Study Design	Randomized, Parallel Group, Placebo Controlled Trial
Public Title of Study	to study the efficacy of pirfenidone in systemic sclerosis related interstitial lung disease
Scientific Title of Study	A randomized controlled trial to compare the efficacy of pirfenidone with placebo in systemic sclerosis related interstitial lung disease

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Nupoor Acharya
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Source of Monetary or Material Support

Source of Monetary or Material Support
> drug is provided by Cipla

Primary Sponsor

Primary Sponsor Details	
Name	Post graduate institute of medical education and research
Address	PGIMER, sector -12,chandigarh 160012
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Nupoor Acharya	PGIMER	department of internal medicine, sector 12 Chandigarh CHANDIGARH	8130966761 nupooracharya88@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
institutional ethics committee	Approved	27/11/2017	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	systemic sclerosis with interstitial lung disease

Intervention / Comparator Agent

Type	Name	Details
Intervention	pirfenidone	one tablet thrice a day (600 mg/day). The dose will be increased to 2 tablets thrice a day (1200 mg/day) after 1 week of initiating treatment, 3 tablets thrice a day (1800 mg/day) after 2 weeks & 4 tablets thrice a day (2400 mg/day) after 3 weeks & will be continued at 2400 mg/day till the end of the study i.e. 6 months.
Comparator Agent	placebo	start with one tablet thrice a day (600 mg/day). The dose will be increased to 2 tablets thrice a day (1200 mg/day) after 1 week of initiating treatment, 3 tablets thrice a day (1800 mg/day) after 2 weeks & 4 tablets thrice a day (2400 mg/day) after 3 weeks & will be continued at 2400 mg/day till the end of the study i.e. 6 months.

Inclusion Criteria

Inclusion Criteria	
Age From	18.00 Year(s)

Age To	70.00 Year(s)
Gender	Both
Details	1.Patients with SSc as diagnosed by the American College of Rheumatology (ACR) criteria, 2013 & patients with other connective tissue diseases who, in parallel, meet the ACR criteria for SSc 2. Presence of ILD on HRCT chest 3. FVC ? 50% 4. Duration of SSc for ?7 years, with onset defined as the appearance of the first nonRaynaud's phenomenon. 5. DLCO 30% to 89% of predicted normal 6. Consenting for participating in study 7. Received no new immunosuppression for last 6 months (on stable doses of immunosuppressants like azathioprine, MMF, cyclophosphamide, methotrexate for > 6 months)

Exclusion Criteria

Exclusion Criteria	
Details	Change in immunosuppressant drugs (except low dose steroids i.e. prednisolone equivalent ?10 mg/day) for ILD in the previous 6 months. 2. Received biologics in the past 3. Persistent leukopenia or thrombocytopenia 4. Pregnant or breastfeeding females 5. Severe PAH (mean pulmonary arterial pressure >55mmHg) requiring drug therapy 6. FEV1/FVC ratio ?65% 7. Uncontrolled congestive heart failure 8. Any other abnormalities noted on chest X-ray or HRCT other than ILD 9. Active infection 10. Inflammatory myopathy 11. Mixed connective tissue disease 12. Smoking during last 6 months 13. Other serious co-morbidities which could compromise the patient's ability to complete the study 14. Abnormal liver function tests (AST/ALT> 3times, bilirubin >1.5)

Method of Generating Random Sequence	Computer generated randomization
Method of Concealment	Sequentially numbered, sealed, opaque envelopes
Blinding/Masking	Participant and Investigator Blinded

Primary Outcome

Outcome	Timepoints
To assess improvement, stabilisation or worsening of interstitial lung disease as measured by change in FVC at 6 months after initiation of therapy with pirfenidone or placebo. Improvement will be defined as improvement in FVC by more than 10%, stabilisation defined as increase or decrease in FVC between 1-10% & worsening will be defined as decline in FVC by more than 10%.	6 months

Secondary Outcome

Outcome	Timepoints
1. To compare the change in Modified Rodnan skin Score (mRSS) from baseline after 6 months of therapy with pirfenidone or placebo 2. To compare the improvement in 6MWT after 6 months of therapy with pirfenidone or placebo. 3. To compare the change in Mahler's transient	6 months

	dyspnea index (TDI/BDI) after 6 months of therapy with pirfenidone or placebo. 4. To compare the change in the levels of TGF-? & TNF-? in the serum after 6 months of therapy with pirfenidone or placebo.
Target Sample Size	**Total Sample Size=**50 **Sample Size from India=**50 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	N/A
Date of First Enrollment (India)	01/02/2018
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	none yet
Brief Summary	The major life-threatening complications of scleroderma are renal crisis, interstitial lung d arterial hypertension and cardiac involvement. With the use of ACE-inhibitors, cases of scler considerably reduced. Presently a major cause of mortality in SSC is ILD. Despite improvem the response in patients with ILD is not as much as expected. There are many unmet medic SSc ILD. SLS1 and SLS2 has shown some benefit with cyclophosphamide and MMF. But n explored. Pirfenidone is an antifibrotic and anti-inflammatory drug that acts mainly through T beneficial in patients with IPF.There are no randomized trials comparing the efficacy of pirfe systemic sclerosis associated ILD. The present study is undertaken to study the efficacy of p SSc with ILD and to study the effects of these drugs on PFTs, HRCT changes, cytokines lev the potential adverse effects of these drugs. This will be a single center, prospective randomized , double blinded, controlled study. The s be carried out on 50 consecutive consenting patients of systemic sclerosis with ILD recruited of PGIMER Chandigarh, India, a tertiary care hospital.The duration of study will be 18 month Clinical details including the symptoms and clinical findings and laboratory parameters inclu function tests (RFT), liver function tests (LFT), urine routine and microscopic, PFTs, HRCT c and cytokines levels will be performed at initiation of therapy. Functional assessment will be test (6MWT). The patients will be re-assessed on follow up at 3 and 6 months. The change i therapy will also be assessed. The aim of the study is to assess improvement, stabilization o functions with pirfenidone. It will be correlated with the cytokines levels. Change in dyspnoea transitional dyspnoea index (TDI) will be assessed at 6 months Randomization: The study consists of two treatment arms. In the pirfenidone arm, the patien 800 mg three times a day for 6 months. In the placebo arm, patients will receive placebo fo randomization of the patients will be performed. The patients will be randomized in a 1:1 rati

generated randomization sequence into either pirfenidone or placebo arm. Allocation concea using sealed opaque envelopes.