Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Pirfenidone versus placebo in Idiopathic Pulmonary Fibrosis progression: a randomize clinical trial

Protocol summary

Summary

The aim of this study is evaluation of the effect of Pirfenidone in clinical outcome of Idiopathic Pulmonary Fibrosis (IPF) progression This is a single center, double-blind randomized phase 2-3 clinical trial The main inclusion criterion of this study is confirmed IPF by biopsy and The main exclusion criteria are the history of connective tissue disease and deny to participate in this study. We will enroll 40 patients with IPf. Participants will randomly be assigned into intervention and control groups and will receive Pirfenidone (1200 mg daily) and placebo respectively for 3 and 6 months. As the primary outcome of our study, the DLCO and pulmonary function test will be measured before and after the intervention. We will compare the results between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031333044N1**
Registration date: **2017-07-13, 1396/04/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-13, 1396/04/22

Registrant information

Name

Aliasghar Karimi

Name of organization / entity

Fasa University of medical Sceinsces

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Respiratory Diseases Institute, Masih Daneshvar Hospital, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Pirfenidone versus placebo in Idiopathic Pulmonary Fibrosis progression: a randomize clinical trial

Public title

Efficacy of Pirfenidone versus placebo in Idiopathic Pulmonary Fibrosis progression:a randomize clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-Confirmed Idiopathic Pulmonary Fibrosis with lung biopsy 2-UIP view in lung HRCT with unknown cause base of ATS-ERS criteria 3-Agreement to participate in this study Exclusion criteria: 1-Suffering from connective tissue disease 2-occupational exposure to substances that cause lung fibrosis 3-close contact with animals 4-Deny to participate in this study

Age

No age limit

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Participants will randomly be assigned into intervention and control groups by table of random numbers . To reduce the bias, This is a double-blind randomized clinical trial so that patients and investigators not aware about their group.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Darabad , Shahid Bahonar (niyavaran) Ave, Tehran, Iran
City
Tehran
Postal code
Approval date
2015-11-10, 1394/08/19
Ethics committee reference number
IR.SBMU.NRITLD.REC.1394.144

Health conditions studied

1

Description of health condition studied
Idiopathic Pulmonary Fibrosis
ICD-10 code
J84.1
ICD-10 code description
Interstitial pulmonary disease, unspecified

Primary outcomes

1

Description
Total Lung Capacity
Timepoint
Before the intervention, three months after the intervention and six months after intervention
Method of measurement
Body box

Secondary outcomes

1

Description
Functional Lung Capacity
Timepoint
Before the intervention, three months after the intervention and six months after intervention
Method of measurement
Body box

2

Description
SPO2
Timepoint
Before the intervention, three months after the intervention and six months after intervention
Method of measurement
Body box

3

Description
DLCO
Timepoint
Before the intervention, three months after the intervention and six months after intervention
Method of measurement
Body box

Intervention groups

1

Description
Intervention group No.1: pirfenidone (PIRFENEX 200 mg manufactured by Cipla Ltd) will be added to their previous medication. The final dosage of pirfenidone is 1200 mg daily. At first, the drug will start at three times a day (600 mg) and will gradually be given at a dose of 400 mg 3 times a day (1200 mg) over a period of 2 weeks. All patients will be received anti-acid secretion, such as proton pumps inhibitors, Also they should use a sunscreen with spf> = 50.
Category
Treatment - Drugs

2

Description
Intervention group No.2: Placebo will be added to previous medication of these patients
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Masih Daneshvari Hospital

Full name of responsible person
Yusef Gholampour

Street address
Darabad Avenue, Shahid Bahonar roundabout

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Behesti University of Medical Sciences

Full name of responsible person
Yusef gholampour

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Vice chancellor for research, Shahid Behesti University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Respiratory Diseases Institute, Masih Daneshvar hospital, Shahid Beheshti University of medical scie

Full name of responsible person
Yosef Gholampour

Position
Pulmonologist

Other areas of specialty/work

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Masih Daneshvari Hospital, Darabad Avenue, Shahid Bahonar roundabout, Tehran, Iran Tehran

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Yusef Gholampour

Position
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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty