Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effectiveness and side effects of Deep Lung Support capsule as adjuvant treatment with prefenidone compared to placebo on clinical symptoms, pulmonary function tests and serum TGF-β levels in patients with idiopathic pulmonary fibrosis.

Protocol summary

Study aim
Determining the clinical and laboratory effects of Deep Lung Support in patients with idiopathic pulmonary fibrosis (IPF) treated with Pirfenidone

Design
The clinical trial with two intervention groups, with parallel groups, double-blind, on 70 patients, and Random Number Generator software will be used for randomization.

Settings and conduct
Patients with idiopathic pulmonary fibrosis, referring to Shahid Modares and Masih Deneshvari hospitals in Tehran, will be included in the study. The study will be double-blind, and the subjects and outcome assessors will be unaware of the drug or placebo allocation. For this purpose, capsules with the same color, shape, size and smell as Deep Long Support capsules will be used.

Participants/Inclusion and exclusion criteria
Inclusion criteria: being at the age of 40-80 years, FVC>40 and less than or equal to 90%, DLCO>40 and less than or equal to 90%. Exclusion criteria: FEV1/FVC ratio less than 0.8, suffering from other interstitial lung diseases, history of chronic lung disease, active infection, treated with other IPF treatment methods, history of unstable heart or lung disease or worse in the last six months, pregnant and lactating women.

Intervention groups
The intervention group will receive 1 oral capsule of deep lung support, three times a day, and the control group will receive a placebo medicine that contains cellulose and will be similar in shape, size and taste to the capsule of deep lung support. In both groups, Pirfenidone 267 mg, that in the first week 801 mg, in the second week 534 mg and from the third week onwards (maintenance treatment) 801 mg will be consumed three times a day.

Main outcome variables
Clinical symptoms (shortness of breath and cough)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230509058135N1**
Registration date: **2023-05-22, 1402/03/01**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-22, 1402/03/01**
Update count: **0**

Registration date
2023-05-22, 1402/03/01

Registrant information

Name
Sasan Tavana

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 29901

Email address
sasan.tavana@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-10, 1402/02/20

Expected recruitment end date
2023-11-11, 1402/08/20

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effectiveness and side effects of Deep Lung Support capsule as adjuvant treatment with prefenidone compared to placebo on clinical symptoms, pulmonary function tests and serum TGF-β levels in patients with idiopathic pulmonary fibrosis.

Public title
The effect of deep lung support capsule in idiopathic pulmonary fibrosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Forced vital capacity (FVC) greater than 40% and less than or equal to 90% Diffusing capacity of the lungs for carbon monoxide (DLCO) greater than or equal to 40% and less than or equal to 90%
Exclusion criteria:
Having an FEV1/FVC ratio of less than 0.8 (after bronchodilator administration) at screening Suffering from other interstitial lung diseases, history of asthma or chronic lung disease, active infection, being treated with other IPF treatment methods such as immunosuppressives and cytokine regulating agents. History of unstable or worsening heart or lung disease (except IPF) in the past six months Pregnant and lactating women
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
A simple randomization method is used, in which the randomization unit is individual, and random sequence generation software (Random Number Generator software) is used. For concealment, non-transparent sealed envelopes with a random sequence is used . In this method, each random number created is recorded on a card and the cards are placed inside the envelopes in order.In order to maintain the random sequence of the envelopes on the outer surface, the numbering is done in the same order. Finally, the lids of the envelopes are glued and placed in a box. At the time of registration of the participants, based on the order of entry of the eligible participants into the study, one of the envelopes will be opened and the allocated group of that participant will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
This will be a double-blind study in which the participants and the researcher who evaluates the effectiveness of the drug will be unaware of the outcome of the variables. For this purpose, a capsule with the same shape, size, color and smell as the Deep Long Support capsule will be used as a placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Deputy of research and technology of Shahid Beheshti University of Medical sciences, Shahid Arabi St.,Yemen St., Shahid Chamran Highway.
City
Tehran
Province
Tehran
Postal code
1983969411
Approval date
2023-05-02, 1402/02/12
Ethics committee reference number
IR.SBMU.MSP.REC.1402.032

Health conditions studied

1

Description of health condition studied
Idiopathic Pulmonary Fibrosis
ICD-10 code
J84.112
ICD-10 code description
Idiopathic pulmonary fibrosis

Primary outcomes

1

Description
Clinical symptoms (cough and shortness of breath)
Timepoint
Once before starting treatment and once 3 months after

that

Method of measurement

"Rate of perceived exertion" and "cough symptom score" scales

2

Description

Pulmonary function tests

Timepoint

Once before starting treatment and once 3 months after that

Method of measurement

by spirometry

3

Description

TGF-β serum level

Timepoint

Once before starting treatment and once 3 months after that

Method of measurement

by blood sample testing

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to pirfenidone tablets, each subject in the intervention group will take an oral deep lung support capsule three times a day with water. The way to take pirfenidone is that each capsule contains 267 mg of medicine, the first week: 267 mg capsules three times a day (801 mg daily) the second week: 534 mg capsules three times a day (1602 mg daily) and from the third week onwards (maintenance treatment): 801 mg three times a day (maximum allowed daily dose: 2403 mg) will be prescribed to the patient.

Category

Treatment - Drugs

2

Description

Control group: In this group, in addition to pirfenidone tablets, there will be a placebo that contains cellulose and will be similar to deep lung support capsules in terms of shape, size and taste. One capsule will be given to the patient three times a day.The way to take pirfenidone is that each capsule contains 267 mg of medicine, the first week: 267 mg capsules three times a day (801 mg daily) the second week: 534 mg capsules three times a day (1602 mg daily) and from the third week onwards (maintenance treatment): 801 mg three times a day (maximum allowed daily dose: 2403 mg) will be prescribed to the patient.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres hospital

Full name of responsible person

Sasan Tavana

Street address

Saadat Abad intersection, Yadgar Imam highway

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2207 4087

Email

modarres@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Masih Daneshvari hospital

Full name of responsible person

Sasan Tavana

Street address

Darabad, Shahid Bahonar Street (Niavaran)

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 3000

Email

pr.nritld@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Deputy of research and technology of Shahid Beheshti University of Medical Sciences, Shahid Arabi St.,Yemen St., Shahid Chamran Highway.

City

Tehran

Province

Tehran

Postal code

1983969411
Phone
+98 21 2243 9783
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sasan Tavana
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Shahid Beheshti University of Medical Sciences,Faculty of Medicine, Koodak Yar St., Daneshjoo Blvd., Velenjek
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 23871
Email
sasan.tavana@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sasan Tavana
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Shahid Beheshti University of Medical Sciences,Faculty of Medicine, Koodak Yar St., Daneshjoo Blvd., Velenjek
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 23871
Email
sasan.tavana@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Parinaz Partovi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
Shahid Beheshti University of Medical Sciences,Faculty of Medicine, Koodak Yar St., Daneshjoo Blvd., Velenjek
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 23871
Email
parinaz.pt68@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available