

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparison of the effect of continuous and interval exercise on respiratory and inflammatory indicators of patients with Interstitial lung disease (ILD) candidates for lung transplantation

Protocol summary

Study aim

Comparison of the effect of continuous and interval exercise on respiratory and inflammatory indicators of patients with Interstitial lung disease (ILD) candidates for lung transplantation

Design

Clinical trial with a control group, with parallel groups, a blinded, randomized, phase 3 on 30 patients, random number table and individual randomization unit were used for randomization.

Settings and conduct

This study is a blind strain and only the researchers responsible for data collection and analysis are not aware of the allocation of groups. A total of 30 patients referred to Masih Deneshvari Hospital in Tehran, Iran will be evaluated. Control group patients do 30 minutes of continuous exercises (treadmill) with 60% of the maximum exercise capacity. In the intervention group, interval exercises include 2 minutes of activity with an intensity of 80% of the maximum exercise capacity, and 2 minutes of recovery with an intensity of 50% (by treadmill). The duration of the exercises will be 30 minutes and over a period of 10 days.

Participants/Inclusion and exclusion criteria

Inclusion criteria include age above 18, consent to participate in the study, BMI in the range of 19-25, muscle force of hip flexors and knee extensors at least 4 out of 5, and patients undergoing oxygen therapy. Exclusion criteria include having pulmonary hypertension, PAP above 40, musculoskeletal problems limiting exercise.

Intervention groups

Patients in the control group perform 30 minutes of continuous exercises (treadmill) with 60% of the maximum exercise capacity. In the intervention group, interval exercises include 2 minutes of activity with an intensity of 80% of the maximum exercise capacity, and

2 minutes of recovery with an intensity of 50%. (by treadmill).

Main outcome variables

Maximum exercise capacity, quality of life, shortness of breath and fatigue, PIMAX and PEMAX, DLCO, FEV1, FVC, CRP, ESR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160516027929N12**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **prospective**

Last update: **2023-01-21, 1401/11/01**

Update count: **0**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Atefeh Fakharian

Name of organization / entity

National research institute of tuberculosis and lung diseases

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2541

Email address

afakharian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01
Expected recruitment end date
2023-12-22, 1402/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of continuous and interval exercise on respiratory and inflammatory indicators of patients with Interstitial lung disease (ILD) candidates for lung transplantation

Public title
Comparison of continuous and intermittent exercise in patients with interstitial lung disease (ILD)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age older than 18
Consent to participate in the study
BMI in the range of 19 to 25
Muscle force of hip flexors and knee extensors at least 4 out of 5
Patients under oxygen therapy
Exclusion criteria:
Pulmonary hypertension PAP above 40
Musculoskeletal problems limiting exercise

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done with a simple randomization method using a table of random numbers and an individual randomization unit. For randomization, we use a table consisting of random numbers 1 to 8. Each of the figures in this table is repeated the same on average. There is no discernible pattern of numerical values. In this method, each figure is assigned to a treatment group. We start from the first row of the table and move down row by row. For the two treatments that will be performed, we put numbers 1 to 4 for treatment A and numbers 5 to 8 for treatment B. We continue the above process until two groups are complete.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is a blind strain and in order to prevent any kind of possible complications, the specialist doctor and the clinical caregiver are fully aware of the specialty of

the treatment groups. Patients participating in the study were not blinded to the type of treatment they received. Only the researchers responsible for data analysis are not aware of the allocation of different study groups. Patient information will be provided to the data analyst in coded form in separate files.

Placebo

Not 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

Next to Taleghani Hospital, Yemen Street , Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2023-01-08, 1401/10/18

Ethics committee reference number

IR.SBMU.NRITLD.REC.1401.107

Health conditions studied

1

Description of health condition studied

Interstitial lung disease (ILD)

ICD-10 code

J84.1

ICD-10 code description

Other interstitial pulmonary diseases with fibrosis

Primary outcomes

1

Description

Plmax

Timepoint

The first day of training and the final day

Method of measurement

Body box

2

Description

PEmax

Timepoint

The first day of training and the final day

Method of measurement

Body box

3

Description

FEV1

Timepoint

The first day of training and the final day

Method of measurement

Spirometry

4

Description

FVC

Timepoint

The first day of training and the final day

Method of measurement

Spirometry

5

Description

TLC

Timepoint

The first day of training and the final day

Method of measurement

Spirometry

6

Description

Maximum sports capacity

Timepoint

The first day of training and the final day

Method of measurement

Six-minute walk test

7

Description

Shortness of breath

Timepoint

The first day of training and the final day

Method of measurement

Based on the Borg scale

8

Description

CRP

Timepoint

The first day of training and the final day

Method of measurement

Evaluation of laboratory tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, interval exercises include 2 minutes of activity with an intensity of 80% of the maximum exercise capacity, and 2 minutes of recovery with an intensity of 50% (by treadmill). Before starting their exercise program, patients do 5 minutes of warm-up exercises with an intensity of 70% of the maximum HR and at the end, they will do a 5-minute cool-down exercise with an intensity of 20-30% of the maximum HR. The duration of the exercises will be 30 minutes and over a period of 10 days.

Category

Rehabilitation

2

Description

Control group: Patients in the control group perform 30 minutes of continuous exercises (treadmill) with 60% of maximum exercise capacity. Before starting their exercise program, patients perform 5 minutes of warm-up exercises with an intensity of 70% of maximum HR and at the end, cool down exercises for 5 minutes. They will do 20-30% maximum HR intensity for 30 minutes during 10 days.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Atefeh Fakharian

Street address

Masih Daneshvari Hospital, Daar Abad

City

Tehran

Province

Tehran

Postal code

1956944413

Phone

+98 21 2712 2102

Email

fakharian_2005@yahoo.com

Sponsors / Funding sources

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Next to Taleghani Hospital, Yemen Street - Shahid
Chamran Highway
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9770
Email
zarghi@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
Atefeh Fakharian
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Masih Daneshvari Hospital, Daar Abad
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2201
Email

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohsen Abedi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
Masih Daneshvari Hospital, Daar Abad
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2020
Email
mohsenabedi110@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Reyhaneh Zahiri
Position
Researcher
Latest degree
Master
Other areas of specialty/work
Biotechnology
Street address
Masih Daneshvari Hospital, Daar Abad
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2020
Email
zahirireyhane@gmail.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