Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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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

PImax

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
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Masih Daneshvari Hospital, Daar Abad
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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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

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Person responsible for scientific inquiries

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Assistant Professor

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Person responsible for updating data

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Researcher

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Biotechnology

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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