

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Effects of 8 weeks of combined aerobic and resistive exercise on fat percentage, quality of life and fatigue in patients with pulmonary sarcoidosis

Protocol summary

Summary

Objective: The effect of 8 weeks of aerobic and resistance training on body composition, perceived exertion fatigue and improve muscle strength in patients with sarcoidosis Study design: Randomized, double-blind, phase II trial Study population: all patients referred to the rehabilitation unit of Masih daneshvari hospital with pulmonary sarcoidosis. inclusion criteria: patients with pulmonary sarcoidosis; Complaints of fatigue or shortness of breath during activities; Residence in Tehran Exclusion criteria: coronary heart disease; retinal involvement; oxygen dependence in rest; Orthopedic disorders; The reluctance of patients to participate in the study; Unstable metabolic diseases. Sample size: 30 subjects (15 patients in each group). Intervention or interventions studied: In both groups of patients, standard medical treatment was prescribed by pulmonologist. Subject in control group prescribed to do aerobic and resistive exercise daily without the supervision of a researcher. In the intervention group supervised aerobic and resistance exercise twice a week for 45 minutes at pulmonary rehabilitation unit f Masih daneshvari hospital. The primary outcome or consequences of the study: the percentage of body fat mass; quality of life score; Fatigue score

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081729405N1**
Registration date: **2016-09-28, 1395/07/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-09-28, 1395/07/07

Registrant information

Name

Shahram Kharabian Masouleh

Name of organization / entity

Masih Daneshvari Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2035

Email address

shahramkharabian@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of 8 weeks of combined aerobic and resistive exercise on fat percentage, quality of life and fatigue in patients with pulmonary sarcoidosis

Public title

Effects of 8 weeks of combined aerobic and resistive exercise on fat percentage, quality of life and fatigue in patients with pulmonary sarcoidosis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients with pulmonary sarcoidosis; Complaints of fatigue or shortness of breath during activities; Residence in Tehran
Exclusion criteria: coronary heart disease; retinal involvement; oxygen dependence in rest; Orthopedic disorders; The reluctance of patients to participate in the study; Unstable metabolic diseases

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Randomization according to block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti Medical University

Street address

6th Floor, Bldg No.2 Shahid beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

City

Tehran

Postal code

Approval date

2015-11-10, 1394/08/19

Ethics committee reference number

IR.SBMU.NRITLD.REC.1394.169

Health conditions studied

1

Description of health condition studied

Sarcoidosis

ICD-10 code

D86.0

ICD-10 code description

Pulmonary sarcoidosis

Primary outcomes

1

Description

Body fat percent

Timepoint

Before and immediately after intervention

Method of measurement

with body composition instrument

Secondary outcomes

1

Description

Saint George quality of life score

Timepoint

Before and immediately after intervention

Method of measurement

standard farsi questionnaire

2

Description

Fatigue score

Timepoint

Before and immediately after intervention

Method of measurement

Fatigue Severity Scale

Intervention groups

1

Description

Intervention group: medication and two sessions per week supervise aerobic and resistive exercise in hospital rehabilitation unit

Category

Rehabilitation

2

Description

Control group: medication and exercise education

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

National research institute of tuberculosis and lung diseases

Full name of responsible person

Saba karimzadeh

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahid Beheshti Medical University

Full name of responsible person

Afshin Rezghi

Street address

7th Floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran. Post code: 198396-3113

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 of Shahid Beheshti Medical University

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

National Research Institute of Tuberculosis and Lung Diseases

Full name of responsible person

Shahram Kharabian Masouleh

Position

Sports and exercise medicine specialist

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

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Shahram kharabian masouleh

Position

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Person responsible for updating data

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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