Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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)

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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 spesialist

Other areas of specialty/work

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

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Other areas of specialty/work

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Web page address

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