

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of changes in Vo2 max after 8 weeks of exercise (on straight, downhill and upright surfaces) in patients with COPD

Protocol summary

Study aim

If aerobic exercise is effective on the downhill or uphill level on increasing vo2max and respiratory function in patients with COPD, regular aerobic exercise can be recommended to improve respiratory function in these patients.

Design

This study will be done on 30 patients with COPD, Patients are randomly divided into three groups of 10 people. level group, downhill group and uphill groups.

Settings and conduct

In this study, three groups of sport activities, including flat surface treadmill exercise (level) group and downhill treadmill exercise (downhill) group and uphill treadmill exercise (uphill) group . in this study Treadmill will be used 3 times per week for 8 weeks, and the duration of physical activity per session is between 30 and 45 minutes based on the patient's ability. at the first, an incremental test is performed for each patient .patients O2Sa are continuously controlled during exercise and in patient with fatigue and inability exercise will be stopped . If the SaO2 drops to less than 88%,the patient receives oxygen If the hypoxia is not corrected, the exercise will stop and the patient is excluded from the study. The vo2 max rate will be measured at the beginning of the study and 8 weeks after exercise

Participants/Inclusion and exclusion criteria

Patients with COPD and body mass index of 19 to 24 without other medical problems, such as heart disease, (including myocardial infarction, myocardial ischemia, cardiac arrhythmia), chronic diseases of the liver, kidney, digestive , musculoskeletal, and central nervous system.

Intervention groups

Level group and downhill group and uphill group: In each group, exercise will be performed 3 times a week for 8 weeks using a treadmill for 30 to 45 minutes.

Main outcome variables

Maximum rate of oxygen consumption (vo2max)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042514N5**

Registration date: **2020-05-31, 1399/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-31, 1399/03/11**

Update count: **0**

Registration date

2020-05-31, 1399/03/11

Registrant information

Name

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Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-10, 1398/10/20

Expected recruitment end date

2020-06-09, 1399/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of changes in Vo2 max after 8 weeks of exercise (on straight, downhill and upright surfaces) in patients with COPD

Public title

Evaluation of changes in Vo2 max after 8 weeks of exercise (on straight, downhill and upright surfaces) in patients with COPD

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

COPD patient BMI: 19-24 Age: 40-60

Exclusion criteria:

Cardiovascular diseases include recent myocardial infarction, myocardial ischemia, cardiac arrhythmia), Chronic liver diseases Digestive diseases Kidney diseases Musculoskeletal, and central nervous system disorders

Age

From **40 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

Street address

Ibn Sina Ave., Jahad Blvd

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Province

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Postal code

7619813159

Approval date

2020-01-01, 1398/10/11

Ethics committee reference number

IR.KMU.AH.REC.1398.162

Health conditions studied

1

Description of health condition studied

Chronic Obstructive Pulmonary Disease

ICD-10 code

J44

ICD-10 code description

Other chronic obstructive pulmonary disease

Primary outcomes

1

Description

Maximum rate of oxygen consumption (vo2max)

Timepoint

At the beginning of the study and 8 weeks after exercise

Method of measurement

Shuttle Standard Protocol

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Exercise on the flat surface treadmill :The program for aerobic exercise in this study is use a treadmill with flat surface for 3 times per week for 8 weeks, and the duration of physical activity per session is between 30 to 45 minutes based on the patient's ability.

Category

Rehabilitation

2

Description

Intervention group: Exercise on the downhill surface treadmill :The program for aerobic exercise in this study is use a treadmill with downhill surface for 3 times per week for 8 weeks, and the duration of physical activity per session is between 30 to 45 minutes based on the patient's ability.

Category

Rehabilitation

3

Description

Intervention group: Exercise on the uphill surface treadmill :The program for aerobic exercise in this study is use a treadmill with uphill surface for 3 times per week for 8 weeks, and the duration of physical activity per

session is between 30 to 45 minutes based on the patient's ability.

Category

Rehabilitation

Recruitment centers**1****Recruitment center****Name of recruitment center**

Afzalipour Hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman 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**

Kerman University of Medical Sciences

Full name of responsible person

Dr Rostam Yazdani

Position

Professor

Latest degree

Subspecialist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No subscription required

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available