Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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

Halimeh Kameshki

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
City
Kerman
Province
Kerman
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

Kerman University of Medical Sciences

Full name of responsible person

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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

Other areas of specialty/work

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Person responsible for updating data

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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