

# 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

Halimeh Kameshki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3281 8065

##### Email address

halimeh.kameshki@gmail.com

##### 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**

Dr Rostam Yazdani

**Street address**

Afzalipour Hospital, Emam Khomeini Highway

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drryazdani@yahoo.com

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Davoud Kalanter

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Drshahrzadmirhosseini@gmail.com

**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**

Internal Medicine

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**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

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr shahrzad mirhosseini

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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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