

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparison of the affect of an aerobic exercise on the downhill, level and uphill surface together, on the leptin/adiponectin ratio in COPD patients

#### Protocol summary

##### Study aim

If the aerobic exercise activity is effective on the downhill or uphill levels, increasing the leptin to adiponectin ratio and respiratory function in patients with COPD, regular aerobic exercise can be ecommended to improve respiratory function in these patients.

##### Design

This study was conducted on 30 patients with COPD, randomly divided into three groups of 10 people. Level group and downhill group and uphill group

##### Settings and conduct

In this study, three groups of sports activities, including treadmill flat surface exercise (level) and treadmill surface slope exercise (downhill) and treadmill high level exercise (uphill) in this study uses treadmill, 3 times per week for 8 weeks, and the duration of physical activity per session is between 30 and 40 minutes based on the patient's ability. Prior to each patient, an incremental test is performed during exercise, SaO<sub>2</sub> patients are continuously controlled and in the event of fatigue and inability of the patient to interrupt exercise. If the SaO<sub>2</sub> drops to less than 88%, the patient receives oxygen and if the hypoxia is not corrected, the activity is discontinued and the patient is excluded from the study. The blood sample was taken before and after exercise, and the Leptin and Adiponectin levels were measured

##### Participants/Inclusion and exclusion criteria

Patients with COPD and body mass index of 19 to 24 non-patients with 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 is performed using treadmill 3 times per week for 8 weeks and for 30 to 40 minutes

##### Main outcome variables

Leptin; Adiponectin

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190127042514N3**

Registration date: **2020-01-13, 1398/10/23**

Registration timing: **retrospective**

Last update: **2020-01-13, 1398/10/23**

Update count: **0**

##### Registration date

2020-01-13, 1398/10/23

##### 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

2019-04-25, 1398/02/05

##### Expected recruitment end date

2019-11-06, 1398/08/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the affect of an aerobic exercise on the downhill, level and uphill surface together, on the leptin/adiponectin ratio in COPD patients

2019-03-18, 1397/12/27

**Ethics committee reference number**  
IR.KMU.AH.REC.1397.173

### Public title

Comparison of the affect of an aerobic exercise on the downhill, level and uphill surface together, on the leptin/adiponectin ratio in COPD patients

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

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

#### Exclusion criteria:

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

### 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

## 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

Serum Leptin levels

#### Timepoint

Blood samples were taken from patients before and after exercise, and their leptin levels were measured and leptin / adiponectin ratios measured and compared before and after exercise.

#### Method of measurement

Blood serum sample

### 2

#### Description

Serum Adiponectin levels

#### Timepoint

Blood samples were taken from patients before and after exercise, and their adiponectin levels were measured and leptin / adiponectin ratios measured and compared before and after exercise.

#### Method of measurement

Blood serum sample

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: sports activity on the flat surface treadmill. The program for aerobic exercise in this study, using a treadmill on a flat surface, 3 times per week for 8 weeks, and the duration of physical activity per session is between 30 to 40 minutes based on the patient's ability.

#### Category

Rehabilitation

### 2

#### Description

Intervention group: sports activity on the downhill surface treadmill .The program for aerobic exercise in this study, using a treadmill on a downhill surface, 3 times per week for 8 weeks, and the duration of physical activity per session is between 30 to 40 minutes based on the patient's ability.

**Category**

Rehabilitation

**3**

**Description**

Intervention group: sports activity on the uphill surface treadmill.The program for aerobic exercise in this study, using a treadmill on a uphill surface, 3 times per week for 8 weeks, and the duration of physical activity per session is between 30 to 40 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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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Dr Davoud Kalanter

**Street address**

Ibn Sina Ave ,Jahad Blvd

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a.alinaghi.langari@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

No

**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

**Street address**

Kerman University of Medical Sciences , Haft Bagh e

Alavi

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**Province**

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**Person responsible for scientific 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****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Ahmad Alinaghi Langari

**Position**

Student

**Latest degree**

A Level or less

**Other areas of specialty/work**

Internal Medicine

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13555-76169

**Phone**

+98 34222250

**Email**

a.alinaghi.langari@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

article

**When the data will become available and for how long**

Get started since 1399

**To whom data/document is available**

For researchers at university institutes

**Under which criteria data/document could be used**

In order to facilitate future research

**From where data/document is obtainable**

dr yazdani

**What processes are involved for a request to access data/document**

Research Council Letter

**Comments**