

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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, SaO₂ patients are continuously controlled and in the event of fatigue and inability of the patient to interrupt exercise. If the SaO₂ 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)

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+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

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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

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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

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Person responsible for scientific inquiries

Contact

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Latest degree

Subspecialist

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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**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

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