

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the affect of an aerobic exercise on the level surface downhill , and uphill surface together on the apolipoprotein A-1/apolipoprotein B ratio in COPD

Protocol summary

Study aim

If the aerobic exercise activity is effective on the downhill or uphill levels, increasing the Apolipoprotein A1 to Apolipoprotein B 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 Apolipoprotein A1 and Apolipoprotein B 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

Apolipoprotein B Apolipoprotein A1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042514N2**

Registration date: **2019-04-10, 1398/01/21**

Registration timing: **prospective**

Last update: **2019-04-10, 1398/01/21**

Update count: **0**

Registration date

2019-04-10, 1398/01/21

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

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 level surface downhill , and uphill surface together on the apolipoprotein A-1/ apolipoprotein B ratio in COPD

Public title
Comparison of the effect of aerobic exercise activity on the sloping surface, flat surface and uphill on Apolipoprotein A1 to Apolipoprotein B ratio 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 kidney diseases digestive 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
2019-03-18, 1397/12/27

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

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 ApolipoproteinB levels

Timepoint

Blood samples were taken from patients before and after exercise, and their Apolipoprotein B levels were measured and Apolipoprotein A1/ Apolipoprotein B ratios measured and compared before and after exercise.

Method of measurement

blood serum sample

2

Description

serum Apolipoprotein A1 levels

Timepoint

Blood samples were taken from patients before and after exercise, and their Apolipoprotein A1 levels were measured and Apolipoprotein A1/ Apolipoprotein B ratios measured and compared before and after exercise.

Method of measurement

blood 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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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?
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
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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