

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Comparison between the acute effects of intermittent hypoxia and aerobic exercise on the nitric oxide value, blood pressure and the respiratory function in Apnea

Protocol summary

Study aim

The aim of this study is comparing the acute effects of activity and periodic hypoxia on the nitric oxide, blood pressure and the pulmonary function in patient of obstructive sleep apnea.

Design

This research is semi-experimental with pretest and posttest interference. The time for each intervention will be randomly and at least three days will be between two interventions

Settings and conduct

11 males will select with least four options of inventory STOP-BAKG questionnaires. They will perform Aerobic exercise on treadmill with 0/070 hart rate reserve in 40 min and inhaled intermittently 5 min normoxic and hypoxic 0/011 air for an hour. Nitric oxide, blood pressure and lung function will measured before and after interventions. SPSS22 ,Kolmogorov Smirnov, ANOVA and Pearson was used. The significance level was considered 0.05 in all tests.

Participants/Inclusion and exclusion criteria

Without respiratory infection, without uncontrolled diabetes or hypertension, without bedridden for Apnea since three months ago, lock of smoking, daily mobility without absolute rest. Absenteeism in any sessions, voluntary exit.

Intervention groups

They will perform aerobic exercise on treadmill with intensity of 70 percent hart rate reserve, along 40 minutes. In intermittent hypoxia, subjects will inhaled intermittently 5 minutes normoxic air and hypoxic 11 percent air at sitting position for an hour. Nitric oxide, blood pressure and lung function will measure before and after interventions.

Main outcome variables

We expect that aerobic exercise protocol of the hypoxia periodic activity, nitric oxide and blood pressure systolic

in apnea will improve. This method has less limitations in comparison with regular exercise at the same time. Expect to fulfill the aim of regular practice for sick, disabled and older applicant.

General information

Reason for update

Acronym

PEFR,TV,NO, FVC, FEV1, FEV1/FVC

IRCT registration information

IRCT registration number: **IRCT20190718044267N1**

Registration date: **2019-08-18, 1398/05/27**

Registration timing: **prospective**

Last update: **2019-08-18, 1398/05/27**

Update count: **0**

Registration date

2019-08-18, 1398/05/27

Registrant information

Name

iran Acbari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 9265 ext. 222

Email address

ronak.latifnezhad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-07, 1398/07/15

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the acute effects of intermittent hypoxia and aerobic exercise on the nitric oxide value, blood pressure and the respiratory function in Apnea

Public title

Comparison between the acute effects of intermittent hypoxia and aerobic exercise on the nitric oxide value, blood pressure and the respiratory function in Apnea

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

without respiratory infection, without uncontrolled diabetes or hypertension, without bedridden for Apnea since three months ago, lack of smoking, daily mobility without absolute rest.

Exclusion criteria:

Acute illness, have absenteeism in sessions, voluntary departure

Age

From **19 years** old to **31 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **2**

Each of samples randomly will perform two interventions

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Crossover

Other design features

the research is semi-experimental with pretest and posttest interference.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Sport sciences Research Institute

Street address

No. 3, Fifth Alley, Miremad Street, Motahari St.,

City

Tehran

Province

Tehran

Postal code

1587958711

Approval date

2019-01-23, 1397/11/03

Ethics committee reference number

IR.SSRC.REC.1397.016

Health conditions studied**1****Description of health condition studied**

Obstructive Sleep Apnea

ICD-10 code

X00

ICD-10 code description

Exposure to uncontrolled fire in building or structure

Primary outcomes**1****Description**

Increased levels of nitric oxide in both aerobic and periodic hypoxia

Timepoint

Before and after each interventions

Method of measurement

Measurement of serum nitric oxide level using ELISA method

Secondary outcomes**1****Description**

Systol blood pressure, diastolic blood pressure and lung function

Timepoint

Before and after each intervention

Method of measurement

Digital pressure mussear and spirometers

Intervention groups**1****Description**

Intervention group: They will perform aerobic exercise on treadmill with intensity of 0/070 hart rate reserve, along 40 minutes. In intermittent hypoxia, subjects will inhale

intermittently 5 minutes normoxic air and hypoxic (0/011) air at sitting position for an hour.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Univercity

Full name of responsible person

Ronak Latifnezhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Personal Grant is not used

Grant code / Reference number

0000

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

No

Title of funding source

Physical Education Laboratory, Faculty of Physical Education and Sport University of Razi University

Proportion provided by this source

60

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

2

Sponsor

Name of organization / entity

The University of Razii

Full name of responsible person

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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**

The University of Shahrood

Full name of responsible person

Ronak Latifnezhad

Position

Unemployed

Latest degree

Master

Other areas of specialty/work

Physiology of exercise

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available