

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of 8 weeks of aerobic exercise under hypoxia and normoxia on plasma irisin levels and insulin resistance in men with metabolic syndrome

Protocol summary

Study aim

1- Determining the effect of 8 weeks of aerobic exercise in hypoxic and neuromoxic conditions on plasma irisin level in overweight people. 2- Determining the effect of 8 weeks of aerobic exercise in hypoxic and neuromoxic conditions on the index of insulin resistance in overweight people.

Design

In order to collect the subjects, a call for participation in research was installed at the university level. Visitors were asked to complete a health questionnaire and level of physical activity. Research from people with a history of cardiovascular disease, high blood pressure, diabetes, smoking, or certain medications was barred from participating in the study. Then, using the information of the questionnaire and observing the criteria for entering the research; Fourteen Razi University students in the 20- to 30-year-old age group who volunteered for all stages of the study were grouped together. In this study, the control group was not considered.

Settings and conduct

All stages of the exercise were performed in the laboratory of the Faculty of Sports Sciences of Razi University.

Participants/Inclusion and exclusion criteria

Exit conditions; Specific cardiovascular, respiratory, renal diseases; History of mountaineering in 6 months before the start date of the research Admission requirements: bmi > 25

Intervention groups

Hypoxic training group in hypoxic tent Aerobic exercise group

Main outcome variables

Changes in blood irisin levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200512047407N1**

Registration date: **2020-09-23, 1399/07/02**

Registration timing: **retrospective**

Last update: **2020-09-23, 1399/07/02**

Update count: **0**

Registration date

2020-09-23, 1399/07/02

Registrant information

Name

peman mohamadi

Name of organization / entity

The university of razi kermanshah

Country

Iran (Islamic Republic of)

Phone

+98 83 8425 2887

Email address

payman_mohammadi@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-30, 1398/11/10

Expected recruitment end date

2020-02-08, 1398/11/19

Actual recruitment start date

2020-01-30, 1398/11/10

Actual recruitment end date

2020-02-08, 1398/11/19

Trial completion date

2020-02-13, 1398/11/24

Scientific title

The effect of 8 weeks of aerobic exercise under hypoxia and normoxia on plasma irisin levels and insulin resistance in men with metabolic syndrome

Public title

The effect of 8 weeks of aerobic exercise under hypoxia and normoxia on plasma irisin levels and insulin resistance in men with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Lack of specific cardiovascular, respiratory and kidney diseases
3- No history of mountaineering in 6 months before the start date of the research

Exclusion criteria:

Sports activity in the last 6 months
Use of special medication during the last 6 months
History of participating in continuous mountaineering activities

Age

From **20 years** old to **30 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **14**

Actual sample size reached: **14**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee

Street address

Kermanshah, Zan Boulevard, Ab Street

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kermanshah

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Kermanshah

Postal code

323138875

Approval date

2020-01-26, 1398/11/06

Ethics committee reference number

IR.RAZI.REC.1398.005

Health conditions studied

1

Description of health condition studied

Obesity and overweight

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Iris is a myocaine 112 amino acid that was recently discovered in 2012. Irisin is a hormone stimulated by exercise that is secreted by skeletal muscle in white mice and humans, and stimulates the conversion of white adipose tissue to quasi-brown adipose tissue, which is the conversion of systemic metabolism by increasing energy costs. Improves

Timepoint

Beginning and end of 8 weeks

Method of measurement

Start with 8 weeks using blood sampling and measuring kits...

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the hypoxia group, a hypoxia tent was used to create hypoxia conditions. It had a tent, a compressor to dilute the oxygen concentration, a sensor to determine the oxygen concentration according to the required height, a pulse oximeter device to monitor the blood oxygen level, a time adjustment system program to perform the exercise program according to the desired time. The hypoxia group performed their training according to the training protocol defined for research in oxygen concentration equal to 15% and with a height of 2700 meters inside the tent. In all stages of training, training schedule, training intensity, heart rate and pedaling frequency of the subjects were monitored and recorded in seconds by the monitoring system connected to the Monarch bicycle. The aerobic training group performed this exercise with the same intensity and protocol in space.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi University's School of Sports Science

Full name of responsible person

peyman mohamadi

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Kermanshah, Zan Boulevard, Ab Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Razi University

Full name of responsible person

mohamad azizi

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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

Razi University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Razi University

Full name of responsible person

peyman mohamadi

Position

University student

Latest degree

Master

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

Not applicable

Informed Consent Form

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

Clinical Study Report

Not applicable

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