

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Sep 2026

The interaction effect of aerobic exercise and vitamin D supplementation on serum levels of apelin, vaspin and inflammatory factors in postmenopausal women with metabolic syndrome

Protocol summary

Study aim

Evaluation of the interactional effect of aerobic exercise and vitamin D supplementation on serum levels of apelin, vaspin and inflammatory factors in postmenopausal women with metabolic syndrome

Design

For this purpose, 48 postmenopausal women with metabolic syndrome will be randomly divided into four groups: aerobic training+ vitamin D supplementation, aerobic training, vitamin D supplementation and control. Supplementation included approximately 50,000 IU or placebo per week for eight weeks. The aerobic training protocol includes 40 to 60 minutes of aerobic exercise with a maximum intensity of 60 to 75% of the heart rate maximum, 3 times a week for eight weeks.

Settings and conduct

This clinical trial study will be conducted on the effects of aerobic training with Vit D supplementation on metabolic syndrome patients of Kermanshah in pre-test and post-test form, under the supervision of the Faculty of Physical Education of Sanandaj Branch of Azad University

Participants/Inclusion and exclusion criteria

Inclusion criteria will include evaluation of metabolic syndrome based on ATPIII criteria, being in menopause age, 25-OHD serum levels between 10 and 20 ng/ml, not having a specific diet and regular exercise program in the past year. Exclusion criteria include; presence of other cardiovascular disease, surgical treatment of obesity or severe weight loss, and the presence of any other chronic disease or skeletal disorders

Intervention groups

Aerobic training (placebo); Vitamin D supplementation (no AT); Aerobic training with vitamin D supplements (AT+Vit D); and Control (placebo+no AT)

Main outcome variables

levels of vitamin D, lipid profile, body composition, blood pressure, insulin, glucose, vaspin, apelin, interleukin-6,

interleukin beta-1, tumor necrosis factor alpha, C-reactive protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200122046217N1**

Registration date: **2020-08-14, 1399/05/24**

Registration timing: **retrospective**

Last update: **2020-08-14, 1399/05/24**

Update count: **0**

Registration date

2020-08-14, 1399/05/24

Registrant information

Name

Parivash Najafi nazar abadi

Name of organization / entity

No.9, Adab Ave, Pasdaran Blvd, Islamic Azad University Sanandaj Branch

Country

Iran (Islamic Republic of)

Phone

+98 87 3328 8661

Email address

pnajafi1354@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-10, 1399/04/20

Expected recruitment end date

2020-08-10, 1399/05/20

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The interaction effect of aerobic exercise and vitamin D supplementation on serum levels of apelin, vaspin and inflammatory factors in postmenopausal women with metabolic syndrome

Public title
The effect of exercise and vitamin D in postmenopausal women with metabolic syndrome

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
confirmation of metabolic syndrome based on ATPIII criteria Not having a specific diet and regular exercise program in the past year 25-OHD serum levels between 10 and 20 ng/ml Being in menopause age
Exclusion criteria:
Presence of other cardiovascular disease Surgical treatment of obesity Presence of any other chronic disease or skeletal disorders severe weight loss

Age
From **50 years** old to **60 years** old

Gender
Female

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In the present study, a table of random numbers will be used for randomization. In which subjects are randomly assigned to separate groups to compare the effects of intervention methods.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

No. 8, Pasdaran Blvd, Sanandaj Province, Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

6617913446

Approval date

2020-01-07, 1398/10/17

Ethics committee reference number

IR.MUK.REC.1398.241

Health conditions studied

1

Description of health condition studied

Metabolic syndrome disease

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

Primary outcomes

1

Description

Vitamin D levels

Timepoint

Prior to the beginning and at the end of the study

Method of measurement

By blood sampling

2

Description

Anthropometric indices

Timepoint

Before the study starts and after the study ends

Method of measurement

Using INBODY test

3

Description

Lipid profile

Timepoint

Before the study starts and after it ended.

Method of measurement

Blood sampling

4

Description

Vaspin

Timepoint

Before the study starts and after it ended.

Method of measurement

Blood sampling

5

Description

Apelin

Timepoint

Before the study starts and after it ended.

Method of measurement

Blood sampling

6

Description

interleukin-6

Timepoint

Before the study starts and after it ended.

Method of measurement

Blood sampling

7

Description

Interleukin beta-1

Timepoint

Before the study starts and after it ended.

Method of measurement

Blood sampling

8

Description

C- reactive protein

Timepoint

Before the study starts and after it ended.

Method of measurement

Blood sampling

9

Description

Tumor necrosis factor alpha

Timepoint

Before the study starts and after it ended.

Method of measurement

Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The aerobic training + vitamin D supplementation Intervention will be consists of 20-40 minutes of aerobic exercise at 60% - 75% of HRmax, 3 times a week for eight weeks and vitamin D supplementation will be receiving vitamin D (~50000 IU

• week for eight weeks).

Category

Lifestyle

2

Description

Intervention group: Aerobic training consists of 20-40 minutes of aerobic exercise at 60% - 75% of HRmax, 3 times a week for eight weeks.

Category

Lifestyle

3

Description

Intervention group: Vitamin D supplementation includes receiving vitamin D (~50000 IU • week for eight weeks).

Category

Lifestyle

4

Description

Control group: receiving placebo and no aerobic training for eight weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali hospital

Full name of responsible person

Parivash Najafi Nazar Abadi

Street address

Shahid Beheshti Blvd. - Imam Ali Cardiovascular Hospital

City

Kermanshah

Province

Kermanshah

Postal code

6715847145

Phone

+98 83 3836 0295

Fax

+98 83 3836 0043

Email

pnajafi1354@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zaher Etemad

Street address

No. 9, Faculty of Physical Education and Sports
Sciences, Sanandaj, Adab St., Daneshgah Blvd.,
Islamic Azad University, Sanandaj Branch

City

Sanandaj

Province

Kurdistan

Postal code

6616935391

Phone

+98 87 3328 8661

Email

zaher.etemad2020@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University, Sanandaj Branch

Proportion provided by this source

10

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Razi University

Full name of responsible person

Rastegar Hoseini

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No.9, Taqh-Bostan Ave, University Blvd, Razi
University.

City

Kermanshah

Province

Kermanshah

Postal code

6714967346

Phone

+98 83 3427 7605

Email

R.hoseini@razi.ac.ir

**Person responsible for scientific
inquiries**

Contact

Name of organization / entity

Razi University

Full name of responsible person

Rastegar

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No.9, Taqh-Bostan Ave, University Blvd, Razi
University.

City

Kermanshah

Province

Kermanshah

Postal code

6714967346

Phone

009834279265

Email

R.hoseini@razi.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University, Sanandaj Branch

Full name of responsible person

Parivash Najafi Nazar Abadi

Position

PhD Student

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

Street address

No. 9, Faculty of Physical Education and Sports
Sciences, Sanandaj, Adab St., Daneshgah Blvd.,
Islamic Azad University, Sanandaj Branch

City

Sanandaj

Province

Kurdistan

Postal code

6616935391

Phone

+98 66 1693 5391

Email

pnajafi1354@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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data will be record in the SPSS software and will be available.

When the data will become available and for how long

Availability will start nine months after publishing all papers

To whom data/document is available

Only available for researchers in academic and scientific institutions

Under which criteria data/document could be used

All data can be used as reference

From where data/document is obtainable

pnajafi1354@gmail.com

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

If the explanation for data request would be convincing it will be given in 3 days.

Comments

not having any