Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Investigating the effect of eight-week low-intensity endurance training with lower limb blood flow restriction on arterial blood pressure, heart performance, and serum levels of PGC1-a, Klotho, and nitric oxide metabolites in patients with mild hypertension

Protocol summary

Study aim

Determining the effect of eight weeks of low-intensity endurance training with lower limb blood flow restriction on arterial blood pressure, heart function and serum levels of PGC1-a, Klotho and nitric oxide metabolites in patients with mild hypertension.

Design

interventional study with a control group, parallel groups, and double-blinded in non-specific randomness will be used on 60 patients and three groups of 20 people.

Settings and conduct

60 retired people who have Inclusion criteria and refer to the Center for retirees after completing the consent form and performing the Astrand test are divided into 3 groups. Before the train, blood sampling and echocardiography are performed. training is performed thrice a week for 8 weeks, and blood sampling and echocardiography are performed again 24 hours after training. place of study is Kerman University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: systolic blood pressure 130-150 mmHg and diastolic blood pressure> 80 mmHg, not taking blood pressure-lowering drugs, body mass index less than 30, 50-65 years old Exclusion criteria: secondary hypertension، heart, respiratory, kidney, liver, metabolic and other chronic diseases, and smoking, narcotic and alcohol consumption

Intervention groups

1: Control group without exercise and blood flow restriction 2: The group that performs 8 weeks of low-intensity endurance exercise. 3: The group that performs 8 weeks of low-intensity endurance exercise with blood flow restriction.

Main outcome variables

PGC1α; Klotho; serum nitrite; blood pressure ; BMI; respiratory exchange ratio; ventilation ratio; PaCO2; PaO2; Echocardiographic parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230528058311N1**
Registration date: **2023-06-12, 1402/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-12, 1402/03/22**
Update count: **0**

Registration date

2023-06-12, 1402/03/22

Registrant information

Name

Maryam Doustaki Zaboli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 9462 2767

Email address

doostaki@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-07-22, 1402/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of eight-week low-intensity endurance training with lower limb blood flow restriction on arterial blood pressure, heart performance, and serum levels of PGC1-a, Klotho, and nitric oxide metabolites in patients with mild hypertension

Public title

Investigating the effect of eight weeks of low-intensity endurance training with lower limb blood flow restriction on arterial blood pressure and cardiac function in patients with mild hypertension

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:

50 - 64 years old Body mass index (BMI) less than 30 Not consumption of blood pressure drugs systolic blood pressure: 130-150mmHg ; diastolic blood pressure>80 mmHg

Exclusion criteria:

Secondary hypertension Smoking Heart, respiratory, kidney, liver, metabolic, and other chronic diseases

Age

From **50 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Colleagues who participate in biochemical tests and data analysis do not inform about the study groups. Samples sent to the laboratory will be numbered؛ additionally, for an individual who performs the data analysis, the study groups will be indistinctive.

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

The beginning of Haft Bagh Alavi axis, University of Medical Sciences campus

City

kerman

Province

Kerman

Postal code

7616913555

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number

IR.KMU.AH.REC.1402.029

Health conditions studied

1

Description of health condition studied

Method of treaning to prevent high blood pressure and diminish the need to consume antihypertensive drugs.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Serum PGC1α level

Timepoint

Before starting training and 24 hours after the last training session

Method of measurement

Elisa

2

Description

Serum levels of Klotho

Timepoint

Before starting training and 24 hours after the last training session

Method of measurement

Elisa

3

Description

Serum nitrite levels

Timepoint

Before starting training and 24 hours after the last training session

Method of measurement

Photometry

Secondary outcomes

1

Description
Changes in blood pressure
Timepoint
One week after the intervention
Method of measurement
with a mercury barometer

2

Description
Left ventricular ejection fraction
Timepoint
One week after the intervention
Method of measurement
Echocardiography by a cardiologist

3

Description
Changes in biochemical parameters
Timepoint
One week after the intervention
Method of measurement
Elisa

4

Description
Left ventricular fractional shortening
Timepoint
One week after the intervention
Method of measurement
Echocardiography

5

Description
Left ventricular mass
Timepoint
One week after the intervention
Method of measurement
Echocardiography

6

Description
Posterior wall thickness
Timepoint
One week after the intervention
Method of measurement
Echocardiography

7

Description
Relative wall thickness
Timepoint
One week after the intervention
Method of measurement
Echocardiography

8

Description
Isovolumic relaxation time
Timepoint
One week after the intervention
Method of measurement
Echocardiography

9

Description
Mean left atrial pressure
Timepoint
One week after the intervention
Method of measurement
Echocardiography

10

Description
Left ventricular end-systolic diameter
Timepoint
One week after the intervention
Method of measurement
Echocardiography

11

Description
Left ventricular end-diastolic diameter
Timepoint
One week after the intervention
Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention group: a group that rides a stationary bicycle at 50% VO2paek for 3 sessions a week, every other day, and each session is a maximum of 45 minutes for 8 weeks.
Category
Treatment - Other

2

Description
Intervention group: a group that rides a stationary bicycle 3 times a week, every other day, and each session is 45 minutes maximum for 8 weeks, with 50% of VO2paek, while the upper part of the thigh is closed with a cuff, blood flow restriction through closing The cuff will be applied in the proximal part of the thighs. The complete femoral artery occlusion pressure will be estimated through the following formula. Lower body

arterial occlusion (mmHg) = (5.893 × thigh circumference) + (0.912 × systolic blood pressure) + (0.734 × diastolic blood pressure) 220.046 The cuff pressure in the exercises in the first and second weeks will be calculated and applied as 50% of the complete occlusion pressure (AOP).

Category
Treatment - Other

3

Description
Control group: Control group without exercise and blood flow restriction

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Center for retirees of Kerman

Full name of responsible person
Masoud Elahi

Street address
Army Street, Army Alley 12, Retired Cente

City
Kerman

Province
Kerman

Postal code
7617467334

Phone
+98 34 1226 7697

Email
doostaki@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abedin Iranpour

Street address
The beginning of Haft Bagh axis, University of Medical Sciences campus

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5804

Email
Iranpourabedin89@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Kerman University of Medical Sciences

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
Kerman University of Medical Sciences

Full name of responsible person
Hamid Najafi pour

Street address
Tahmasababad intersection

City
Kerman

Province
Kerman

Postal code
7617467334

Phone
+98 34 3226 4071

Email
najfipourh@yahoo.co.uk

Grant name

Grant code / Reference number

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

Title of funding source
Kerman University of Medical Sciences

Proportion provided by this source
40

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

Siavash Jokar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

Street address
At the end of 22 Bahman Blvd., Shahid Bahonar University, Afzalipur Faculty of Medicine

City
Kerman

Province
Kerman

Postal code
7616914115

Phone
+98 34 3132 0500

Email
Sjokar@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Siavash Jokar

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Email
Sjokar@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
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+98 34 3132 0500

Email
Sjokar@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
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
The result of the study will be shared with the participants in the Rubika social network. and it will be published with Print the article.

When the data will become available and for how long
The beginning of the access period for participants in Rubika, immediately after obtaining the results and for the public after the publication of the article from 2025

To whom data/document is available
It will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used
With the permission and discretion of the person in charge of the study, the data will be available to researchers working in academic and scientific institutions.

From where data/document is obtainable
Afzalipur Faculty of Medicine, Department of Physiology by Dr. Siavash Jokar Postal code: 7616914115 Email: Sjokar@gmail.com 09132985770

What processes are involved for a request to access data/document
The study documentation can be accessed by Correspondence with the principal investigator

Comments