# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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)
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+98 34 9462 2767
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**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**
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**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

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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

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**Province**
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7617467334

**Phone**
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**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

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Sjokar@gmail.com

## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
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**