

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### The effect of high-intensity interval training on apelin-dependent mechanism in treated hypertension elderly man

#### Protocol summary

##### Summary

The purpose of this study will be investigation of the effect of high-intensity interval training on mechanism of reduce blood pressure induced apelin in treated hypertension elderly people. The study design will be based on non blinding. Forty five patients will be equally divided and randomized into three groups including high intensity interval training 1 and 2 and control. Inclusion criteria: will be treated hypertension elderly men; no any participant to regular exercise training for 1 year and exclusion criteria: body mass index >28; cardiovascular disease; liver and kidney disease; mental disease; functional limitation( such as osteoarthritis) and cessation of drug use during the study. Protocol of high-intensity interval training number one: including 6 intervals that each interval will be 1.5 minutes at 85-90 % HR reserve and 2 minutes active interval at 50-55%. Other high-intensity interval training including 3 intervals that each interval will be 3.5 minutes at 85-90 % HR reserve and 3.5 minutes active interval at 50-55% that undertaken for 6 weeks. Indicators of nitrate/nitrite, apelin, systolic and diastolic blood pressure will be measured before and after 6 week exercise training.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016092823002N3**

Registration date: **2016-10-24, 1395/08/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-10-24, 1395/08/03

##### Registrant information

##### Name

Alireza Ghardashi Afousi

##### Name of organization / entity

University of Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8201 5031

##### Email address

ghardashi.a@ut.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice President of Research of Tehran University (Faculty of Physical Education and Sport Science)

##### Expected recruitment start date

2016-05-21, 1395/03/01

##### Expected recruitment end date

2016-08-22, 1395/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of high-intensity interval training on apelin-dependent mechanism in treated hypertension elderly man

##### Public title

Interval exercise training and the mechanism of reduced blood pressure

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Including criteria: treated hypertension elderly men; no any participant to regular exercise training for 1 year and exclusion criteria will be: body mass index >28;

cardiovascular disease; liver and kidney disease; mental disease; functional limitation( such as osteoarthritis) and cessation of drug use during the study.

#### **Age**

From **50 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **45**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethic committee of Tehran university (Faculty of Physical Education and Sport Science)

###### **Street address**

Faculty of Physical Education and Sport Science, Above the Intersection Jalal Al-e Ahmad, North Karegar Avenue, Islamic Revolution Square

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2016-05-30, 1395/03/10

##### **Ethics committee reference number**

IR.UT.1395.198

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Hypertension

##### **ICD-10 code**

I10, I11,

##### **ICD-10 code description**

Hypertensive diseases

### **Primary outcomes**

#### **1**

##### **Description**

Apelin

##### **Timepoint**

Before and after 6 week of intervention

##### **Method of measurement**

ELISA

#### **2**

##### **Description**

Nitrate/nitrite

##### **Timepoint**

Before and after 6 week of intervention

##### **Method of measurement**

ELISA

#### **3**

##### **Description**

VO2 peak

##### **Timepoint**

Before and after 6 week of intervention

##### **Method of measurement**

Gas analyser

#### **4**

##### **Description**

Resting heart rate

##### **Timepoint**

Before and after 6 week of intervention

##### **Method of measurement**

Polar beat heart rate

#### **5**

##### **Description**

Systolic and diastolic blood pressure

##### **Timepoint**

Before and after 6 week of intervention (rest, exercise, recovery)

##### **Method of measurement**

sphygmomanometer

#### **6**

##### **Description**

Fat percent

##### **Timepoint**

Before and after 6 week of intervention

##### **Method of measurement**

Caliper- Jackson and Pollock's Equation

#### **7**

##### **Description**

Endothelin-1

##### **Timepoint**

Before and after 6 week of intervention

**Method of measurement**

ELISA

**8****Description**

Maximal heart rate

**Timepoint**

Before and after 6 week of intervention

**Method of measurement**

Polar beat heart rate

**9****Description**

Recovery heart rate

**Timepoint**

Before and after 6 week of intervention (1,2,3 minutes recovery)

**Method of measurement**

Polar beat heart rate

**Secondary outcomes**

empty

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

Intervention group 1: 6 interval (1.5 minutes at 85-90 % HR reserve with 2 minutes active interval at 50-55 % HR reserve)

**Category**

Rehabilitation

**2****Description**

Intervention group 2: 3 interval (3.5 minutes at 85-90% HR reserve with 3.5 minutes at 50-55% HR reserve)

**Category**

Rehabilitation

**3****Description**

Control group: normal condition without any exercise

**Category**

N/A

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ayatalah Ashrafi isfahani hospital

**Full name of responsible person**

Narges Alsadat Zahed

**Street address**

Ayatalah Ashrafi Isfahani hospital, Molavi Crossroads,

Molavi Square

**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice President of Research ( Faculty of Physical Education and Sport Science)

**Full name of responsible person**

Alireza Ghardashi

**Street address**

Faculty of Physical Education and Sport Science, Above the Intersection Jalal Al-e Ahmad, North Karegar Avenue, Islamic Revolution Square.

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice President of Research ( Faculty of Physical Education and Sport Science)

**Proportion provided by this source**

100

**Public or private sector**

empty

**Domestic or foreign origin**

empty

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

empty

**Person responsible for general inquiries****Contact****Name of organization / entity**

University of Tehran

**Full name of responsible person**

Alireza Ghardashi

**Position**

PhD

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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## Sharing plan

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*

## Person responsible for updating data

### Contact

**Name of organization / entity**

University of Tehran

**Full name of responsible person**