

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of combined training and L-arginine ingestion on the serum levels of Adropin, VEGFR-2 and intercellular and vascular adhesion molecules in postmenopausal hypertensive women

#### Protocol summary

##### Study aim

The effect of combined training and L-arginine consumption on serum levels of adropine, VEGFR-2 and cellular and vascular adhesion molecules in postmenopausal women with hypertension.

##### Design

The study is a double-blind, randomized, factorial clinical trial. The target population includes 40 hypertensive postmenopausal women who will be divided into four groups of 10 people. Subjects in the combined exercise group will practice for 8 weeks and three sessions per week. Resistance training will include a set of 15-20 repetitions and the endurance training program will include 20 minutes of walking or running per session. The intensity of the endurance training program is 75-60% of the maximum heart rate. L-arginine supplementation will be taken daily at a rate of 6 grams (three 2-gram servings) by L-arginine and exercise + L-arginine subjects (after breakfast, lunch and dinner) and at the same time by placebo subjects. They take a placebo (white flour capsule).

##### Settings and conduct

Given that the placebo and L-arginine supplement inside the capsule are quite similar participants and researchers are informed of the type of supplement received are not. Sports exercises are performed in Valiasr Sports Club in Tehran.

##### Participants/Inclusion and exclusion criteria

Women in the age group of 50 to 60 years who are menopausal and have high blood pressure. Do not have other cardiovascular diseases and have no restrictions on physical activity. Do not have drug or alcohol addiction.

##### Intervention groups

Subjects after filling out the individual consent form to participate in the research simple random (based on a table of random numbers into four groups) 10 people: 1. Placebo group 2. L-arginine supplement group 3.

Combined exercise group 4. Combined exercise group + L-arginine supplement are divided

##### Main outcome variables

Adropin, VEGFR-2, ICAM-1

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210627051723N1**

Registration date: **2021-07-03, 1400/04/12**

Registration timing: **prospective**

Last update: **2021-07-03, 1400/04/12**

Update count: **0**

##### Registration date

2021-07-03, 1400/04/12

##### Registrant information

##### Name

Rozita Nourbakhsh

##### Name of organization / entity

The University of Tehran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3440 3642

##### Email address

rozita.phd.1355@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-07-16, 1400/04/25

##### Expected recruitment end date

2021-09-06, 1400/06/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of combined training and L-arginine ingestion on the serum levels of Adropin, VEGFR-2 and intercellular and vascular adhesion molecules in postmenopausal hypertensive women

**Public title**

The effect of combined exercise and L-arginine on adropine, VEGFR-2 and adhesive molecules in hypertensive postmenopausal women

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Women 50 to 60 years old with menopause confirmed by a doctor Confirmation of hypertension No other cardiovascular diseases Not participating in regular physical activity in the past year

**Exclusion criteria:**

Having type 2 diabetes Restrictions on physical activity Drug or alcohol addiction

**Age**

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

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The subjects' names are written on separate sheets of paper and placed in a container, then the subjects' names are randomly taken out and placed in the intervention or placebo group. The first 30 names are placed in the intervention group and the rest in the placebo group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to eliminate the error caused by the awareness of the participants and the researcher Study on the type of treatment received and its possible impact on the research outcome We do it blindly in two directions. Because the placebo and L-arginine supplement are placed inside the capsule in exactly the same way, participants and researchers are not aware of the type of supplement they receive.

**Placebo**

Used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of the Faculty of Physical Education and Sports Sciences, University of Tehran

**Street address**

Thirteenth floor, Block A, Central headquarters of the Ministry of Health, Qads town

**City**

Tehran

**Province**

Tehran

**Postal code**

3144685543

**Approval date**

2021-03-14, 1399/12/24

**Ethics committee reference number**

IR.UT.SPORT.REC.1400.005

**Health conditions studied****1****Description of health condition studied**

Hypertension

**ICD-10 code**

I10

**ICD-10 code description**

Essential (primary) hypertension

**Primary outcomes****1****Description**

Adropin

**Timepoint**

First, the end of the study

**Method of measurement**

Kit Elisa

**2****Description**

VEGFR-2

**Timepoint**

First, the end of the study

**Method of measurement**

Kit Elisa

### 3

**Description**

ICAM-1

**Timepoint**

First, the end of the study

**Method of measurement**

Kit Elisa

## Secondary outcomes

### 1

**Description**

Systolic blood pressure

**Timepoint**

First, the end of the study

**Method of measurement**

Mercury blood pressure monitor

### 2

**Description**

Diastolic blood pressure

**Timepoint**

First, the end of the study

**Method of measurement**

Mercury blood pressure monitor

## Intervention groups

### 1

**Description**

Intervention group: L-arginine supplement group (L-arginine supplement daily and at a dose of 6 grams (three servings of 2 grams.))

**Category**

Prevention

### 2

**Description**

Combined exercises will be performed for 8 weeks and three sessions per week. First, resistance training and a few minutes later, endurance training will be performed.

**Category**

Prevention

### 3

**Description**

Intervention group: Combined training group + L-arginine supplement (combined training will be performed for 8 weeks and three sessions per week. First, resistance training and a few minutes later, endurance training. At the same time, L-arginine supplement is taken daily and in the amount of 6 grams (three meals of 2 grams) every day.)

**Category**

Prevention

### 4

**Description**

Control group: Placebo group (not participating in exercise and taking placebo. For 8 weeks, taking L-arginine-like capsules with white flour content (placebo) in the morning, evening and night, made by Darogostar company, in addition to daily activities of life.)

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

Dr. Hendsi Blood Pressure Treatment Clinic

**Full name of responsible person**

Nourbakhsh Rozita

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Next to Erfan Hospital, Shahrdari Square, Saadat Abad

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## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

The University of Tehran

**Full name of responsible person**

Ravasi Ali Asghar

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In front of the university dormitory, Amirabad, North Kargar Street

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

Yes

**Title of funding source**

The University of Tehran  
**Proportion provided by this source**  
100  
**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**  
The University of Tehran  
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## 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)

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

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

### Informed Consent Form

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

### Clinical Study Report

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

### Analytic Code

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

### Data Dictionary

Not applicable