Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 groups10 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)
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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 gro
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 outcomeWe 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 performe.)
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. Hendesi Blood Pressure Treatment Clinic
Full name of responsible person
Nourbakhsh Rozita
Street address
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
Street address
In front of the university dormitory, Amirabad, North Kargar Street
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Province
Tehran
Postal code
1411713135
Phone
+98 21 8874 7884
Email
aaravasi@ut.ac.ir
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

Full name of responsible person

Nourbakhsh Rozita

Position

PHD student

Latest degree

Ph.D.

Other areas of specialty/work

Physiology

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Person responsible for scientific inquiries

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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