

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of L-arginine supplementation on biochemical and anthropometric indices associated with cardiovascular diseases

Protocol summary

Summary

Potential role of L-arginine supplementation as a new effective strategy for weight loss and improving biochemical parameters in obese patients is recently under consideration. To evaluate influence of 8-week oral supplementation of L-arginine on body mass index (BMI), waist circumference (WC), tricep skinfold (TS), subscapular skinfold (SS), systolic blood pressure (SBP), diastolic blood pressure (DBP), plasma level of fasting blood sugar (FBS), glycated hemoglobin (HbA1c), triglyceride (TG), total cholesterol (TC), LDL, HDL, and Malondialdehyde (MDA) in patients with BMI higher than 29.9 or visceral obesity (wc more than 102 cm in men or more than 88 in women). Randomized control trial was performed on 75 (41 men, 34 women) obese patients. Patients were randomized to either L-arginine (3 g tid or 6 g tid) or placebo, respectively for 8 weeks. Anthropometric indices, dietary intake, blood pressure values and biochemical were performed at the baseline and after 8-week intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501183236N6**
Registration date: **2015-02-01, 1393/11/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-01, 1393/11/12

Registrant information

Name

Zohreh Mazloom

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1725 1008

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zmazloom@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences - post Graduate

Expected recruitment start date

2015-01-20, 1393/10/30

Expected recruitment end date

2015-02-19, 1393/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L-arginine supplementation on biochemical and anthropometric indices associated with cardiovascular diseases

Public title

L-arginine supplementation effect on CVDs.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: both sexes; BMI higher than 29.9 kg/m² or visceral obesity (BMI within 25- 29.9 kg/m² and wc more than 102 cm in men or more than 88 in women); acute or chronic inflammation; stable body weight 3 months before the start of the study (based on self report) absence of any current diet or supplement treatment; absence of antidiabetic, antihypertensive, antihyperlipidemic treatment; no history of ischemic

heart disease; and normal renal and liver function.
Exclusion criteria: Unwillingness to continue; the use of tobacco or alcohol during the study; taking any supplements other than the selected intervention; any disease or physiological changes that requires special treatment; failure to follow the intervention designing (not consuming dedicated supplement to the total amount less than 90% predicted or more than 3 days).

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Shiraz University of Medical Sciences

Street address

Zand Street - opposite of Palestine Street - the headquarters of Shiraz University of Medical Sciences

City

Shiraz

Postal code

14336 - 71348

Approval date

2014-12-14, 1393/09/23

Ethics committee reference number

CT-9376-7276

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

Obesity

ICD-10 code

E66.9

ICD-10 code description

Obesity, unspecified

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

weight

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Balance - kg

2**Description**

wc

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Tape - cm

3**Description**

skinfold

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

caliper - mm

4**Description**

Systolic and diastolic blood pressure

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Pressure set manually - mm Hg

5**Description**

fs

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Standard enzymatic method - milligrams per deciliter

6**Description**

TG

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Standard enzymatic method - milligrams per deciliter

7**Description**

TC

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Standard enzymatic method - milligrams per deciliter

8

Description

LDL

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Standard enzymatic method - milligrams per deciliter

9

Description

HDL

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Standard enzymatic method - milligrams per deciliter

10

Description

HbA1c

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Standard enzymatic method - percentage

11

Description

MDA

Timepoint

Before the experiment, eight weeks after intervention

Method of measurement

Standard enzymatic method - micromol per liter

Secondary outcomes

1

Description

BMI

Timepoint

Before and after intervention

Method of measurement

weight divide into height²

Intervention groups

1

Description

L-Arginine 3 g/day 8 weeks

Category

Treatment - Drugs

2

Description

L-arginine 6 g/day 8 weeks

Category

Treatment - Drugs

3

Description

placebo 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari health care center

Full name of responsible person

Street address

City

shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Syyed Basir Hashmi

Street address

Seventh Floor, Office of Research and Technology,
Central Building of Shiraz University of Medical
Sciences, Zand Street, Shiraz

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences, Faculty of
Nutrition and Food Sciences

Full name of responsible person

Arash Dashtabi

Position

Master of Science in Nutrition

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

Department of Nutrition and Food Science,
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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences, Faculty of
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Full name of responsible person

Zohre Mazloom

Position

PhD, nutritional sci - professor

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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