Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

Summary

Potential role of L-arginine supplementation as a new effective strategy for weight loss and improving biochemichal 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), sistolic 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 Malone dealdeid (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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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 anthropometirc 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 than 29.9 kg/m2 or visceral obesity (BMI whithin25- 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
fbs
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 devide into height2

Intervention groups

1

Description
L-Ariginine 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

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Fax

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences, Faculty of Nutrition and Food Sciences

Full name of responsible person
Zohre Mazloom

Position
PhD, nutritional sci - professor

Other areas of specialty/work

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Person responsible for updating data

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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