

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of L- arginine supplementation on the lipid profile, glycemic index and insulin resistance in patients with metabolic syndrome.

Protocol summary

Summary

Objectives: This study is a double blind randomized controlled clinical trial was carried out to evaluate the effect of arginine supplementation on the lipid profile, glycemic control and measures of insulin resistance in patients with metabolic syndrome. Design: In this study, 60 patients with metabolic syndrome (Referred to Yazd Diabetes Center) will be studied With regard to the criteria for entry and exit And most of the samples for possible loss. The participants were randomly divided into two groups (intervention and placebo) And are studied for 12 weeks. Setting and conduct: The intervention group received two 2500 mg sachet arginine and placebo group received 2500 mg sachet containing cellulose compounds after lunch and dinner. main outcome measures: weight, BMI, waist circumference, HbA1c, FBS, Insulin, Insulin Sensitivity, HOMA index, HDL, TG, LDL and total cholesterol was measured before and after 3 months of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120425245N2**

Registration date: **2015-12-30, 1394/10/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-12-30, 1394/10/09

Registrant information

Name

Davood Bahrami

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2015-12-01, 1394/09/10

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of L- arginine supplementation on the lipid profile, glycemic index and insulin resistance in patients with metabolic syndrome.

Public title

The effect of L- arginine supplementation on metabolic syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who agree to participate in the study! Having 3 or more of the ATP III criteria! Aged between 20 to 60. Exclusion criteria: The unwillingness of people to enter the study for any reason! Tobacco and alcohol! BMI above 35 and below 18.5! Pregnancy and lactation! hypersensitivity to the drug or allergy, Follow the special dietary! the use of insulin and Inflammatory

drugs such as corticosteroids over 3 months: History of diabetes are more than 5 years: History of angina: stroke or heart attack in recent years: Chronic kidney disease or severe liver disease: Chronic inflammatory disease and thyroid disease during the past year: Taking any dietary supplement including L- arginine during 2 months before the start of the study.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

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

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Department of Health, Yazd Shahid Sadoughi University of Medical Sciences

City

Yazd

Postal code

8915173143

Approval date

2015-11-14, 1394/08/23

Ethics committee reference number

IR.SSU.SPH.REC.1394.53

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

Metabolic Syndrome

ICD-10 code

-

ICD-10 code description

-

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

Fasting blood sugar

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Autoanalyzer

Secondary outcomes**1****Description**

HbA1C

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

2**Description**

total Cholesterol

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

3**Description**

LDL

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

4**Description**

HDL

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

5**Description**

TG

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

6

Description

INSULIN

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

7

Description

HOMA-IR

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Using insulin and fasting glucose

8

Description

HOMA-B

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Using insulin and fasting glucose

9

Description

QUICKI

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Using insulin and fasting glucose

Intervention groups

1

Description

Intervention group: received two 2500 mg sachet arginine Production of pharmaceutical company Karen after lunch and dinner

Category

Placebo

2

Description

Control group: received 2500 mg sachet containing cellulose compounds Production of pharmaceutical company Karen after lunch and dinner

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Research Center

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Street address

Diabetes Center, Talare Honar alley, Bahonar square

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

for research of Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Street address

Department of Health, Alem square

City

Yazd

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

for research of Yazd Shahid Sadoughi 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

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Davood Bahrami

Position

Student of MSc Health Sciences in Nutrition

Other areas of specialty/work

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Web page address**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