

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Assessment of L-Arginine supplementation on insulin resistanc, sugar and lipid profile in patients with type II diabetes

Protocol summary

Summary

Objectives: Investigate the effect of L-Arginine supplementation on insulin resistance, sugar and lipid profile in patients with diabetes type II. Design: Randomized, double-blind, placebo-controlled study. Setting and conduct: 75 patients with type 2 diabetes were randomly selected according to eligibility criteria. Patients are randomly divided into three groups and were Followed for 90 days. Criteria for inclusion in the study: Suffering from diabetes type 2: Diabetes record between 4-10 years. Fasting glucose range of 160-400 mg/dl. Aged between 30 to 60. Criteria for exclusion from the study: Suffering from Renal, Liver, Parathyroid and GI Diseases. Pregnancy and lactation. Use of insulin, HbA1c<7mg/dl. Intervention: Group one: 3gr/d L-arginine; Group two: 6gr/d L-arginine and Group three placebo. main outcome measures:Height, 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: **IRCT2012071010240N1**

Registration date: **2014-09-24, 1393/07/02**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-09-24, 1393/07/02

Registrant information

Name

Sara Asadi

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 1624 0691

Email address

asadi@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University of Medical Sciences-Yazd, Iran

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2014-01-20, 1392/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of L-Arginine supplementation on insulin resistanc, sugar and lipid profile in patients with type II diabetes

Public title

Assessment of L-Arginine supplementation on insulin resistanc, sugar and lipid profile

Purpose

Supportive

Inclusion/Exclusion criteria

Criteria for inclusion in the study: Suffering from diabetes type 2: Diabetes record between 4-10 years. Fasting glucose range of 160-400 mg/dl. Aged between 30 to 60. Criteria for exclusion from the study: Suffering from Renal, Liver; Parathyroid and GI Diseases. Pregnancy and

lactation. Use of insulin; HbA1c<7mg/dl

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

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)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd Univesity of Medical Sciences Ethics Committee

Street address

Shahid Sadoughi University of Medical Sciences,
Shahid Bahonar Square, Yazd.

City

Yazd

Postal code

8916978477

Approval date

2012-05-09, 1391/02/20

Ethics committee reference number

22422/1/17/پ

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

HbA1c

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

2

Description

Insulin

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Insulin kit

3

Description

Fasting blood sugar

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Autoanalaizer

4

Description

HDL

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

5

Description

LDL

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

6

Description

TG

Timepoint

at the begining of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

7

Description

Cholesterol

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Enzyme colorimetry

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

Anthropometric indicators: weight, height, body mass index, waist circumference

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

Tape and scale

2**Description**

Insulin Resistance

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

HOMA index

3**Description**

Insulin Sensitivity

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

HOMA2 calculator software

4**Description**

Beta cell function

Timepoint

at the beginning of the study and 3 month after intervention

Method of measurement

HOMA2 calculator software

Intervention groups**1****Description**

3gr/d L-arginine for 3 months

Category

Treatment - Drugs

2**Description**

6gr/d L-arginine for 3 months

Category

Treatment - Drugs

3**Description**

3gr/d placebo for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Center, Fasa University of Medical Sciences

Full name of responsible person

Dr. Seyed Javad Siadatan

Street address

Ebne Sina Square.

City

Fasa

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research, Yazd University of Medical Sciences

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Street address

Shahid Bahonar Square

City

Yazd

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

Yes

Title of funding source

Vice chancellor for Research, Yazd 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**

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Sara Asadi

Position

Graduate Student of Health Sciences in Nutrition

Other areas of specialty/work

Street address

Shahid Bahonar Square

City

Yazd

Postal code

Phone

+98 35 1624 0691

Fax

+98 35 1624 0691

Email

asadis_744@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Dr Hasan Mozaffari Khosravi

Position

PhD of nutrition

Other areas of specialty/work

Street address

Shahid Bahonar Square.

City

Yazd

Postal code

Phone

+98 35 1624 0691

Fax

+98 35 1624 0691

Email

mozaffari@ssu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd,
Iran

Full name of responsible person

Sara Asadi

Position

MS student of Health Sciences in Nutrition

Other areas of specialty/work

Street address

Bahonar Square

City

Yazd

Postal code

Phone

+98 35 1624 0691

Fax

+98 35 1624 0691

Email

asadis_744@yahoo.com

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