

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of L-Arginine supplementation on antioxidant enzyme activity of Type 2 Pre-diabetic patients

Protocol summary

Summary

Type of study: randomized double blind clinical trial.
Target Population: Type 2 Pre-diabetic patients that's referred to Endocrine Research Center, Shariati Hospital.
The main objective of the research Effect of L-Arginine supplementation on antioxidant enzyme activity of Type 2 Pre-diabetic. Applicable goals of the research: proposals using oral arginine to improve the health of Type 2 Pre-diabetic patients , according to a result of study Inclusion criteria: tendency to cooperate with research project, Newly diagnosed individuals with pre-diabetes, People with pre-diabetes, a fasting blood sugar of 100 -125mg/ dL or a two-hour blood sugar between 140 to 199 mg/ dL, Range of BMI 25 to 34.9 Kg / m 2, Age: 20 to 50 years, Exclusion Criteria: - Non-compliance supplements taking (more than 10% of supplements it is not been taken .) - The existence of any of the criteria Not allowed to inter criteria - not wanting to continued cooperation Sample size: 46 cases (23 intervention group and 23 control) Intervention: The intervention group patients daily 3 g L - arginine (3 capsules containing 1 g L-arginine) was given and control group intake 3 g placebo every 8 hours for 8 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201211106415N2**

Registration date: **2013-01-02, 1391/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-02, 1391/10/13

Registrant information

Name

Ahmad Saedi Some Olia

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

a_saedi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

1 - a budget that related to the to the thesis of masters degree (15,000,000) 2 -Vice chancellor for research,Tehran University of Medical Sciences

Expected recruitment start date

2012-10-31, 1391/08/10

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L-Arginine supplementation on antioxidant enzyme activity of Type 2 Pre-diabetic patients

Public title

Effect of L-Arginine supplementation on antioxidant status in Pre-diabetic patients .

Purpose

Prevention

Inclusion/Exclusion criteria

A) Inclusion criteria: - tendency to cooperate with research project - Newly diagnosed individuals with pre-diabetes - People with pre-diabetes, a fasting blood sugar

of 100 -125mg/ dL or a two-hour blood sugar between 140 to 199 mg/ dL - Range of BMI 25 to 34.9 Kg / m 2 - Age: 20 to 50 years; B) Not allowed to inter criteria: - Have not past medical history of chronic diseases such as cardiovascular disease, liver disease, thyroid disease, chronic infection, heart attack or stroke in the previous years .- Taking lipid-lowering drugs, blood sugar-lowering drugs, estrogen or progesterone, antibiotics during past year , - Taking any supplements such as L - arginine during the 2 months prior to the study- Smoking - pregnancy or lactation, or menopause - alcohol intake; C) Exclusion Criteria: - Non-compliance supplements taking (more than 10% of supplements it is not been taken .) - The existence of any of the criteria Not allowed to inter criteria - not wanting to continued cooperation

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Not 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 Tehran University of Medical Sciences

Street address

Ethics Committee of Vice chancellor for research, Tehran University of Medical Sciences, Keshavarz Blvd, Ghods st

City

Tehran

Postal code

Approval date

2012-12-03, 1391/09/13

Ethics committee reference number

91-03-161-19260-71342

Health conditions studied

1

Description of health condition studied

pre-diabetic patient

ICD-10 code

R73.0

ICD-10 code description

Impaired glucose tolerancePrediabetes

Primary outcomes

1

Description

Glutathione peroxidase activity level

Timepoint

Before and 2 months after the start of supplementation

Method of measurement

Blood testing (by ELISA kit)

2

Description

Glutathione reductase activity

Timepoint

Before and 2 months after the start of supplementation

Method of measurement

Blood testing (by ELISA kit)

3

Description

Superoxide dismutase activity

Timepoint

Before and 2 months after the start of supplementation

Method of measurement

Blood testing (by ELISA kit)

4

Description

total antioxidant capacity

Timepoint

Before and 2 months after the start of supplementation

Method of measurement

Blood testing (by ELISA kit)

Secondary outcomes

1

Description

Serum concentrations of arginine

Timepoint

Before and 2 months after supplementation

Method of measurement

blood testing

2

Description

Weight

Timepoint

Before and 2 months after supplementation

Method of measurement

Use Scale With Accuracy 100g

3

Description

height

Timepoint

Before and 2 months after supplementation

Method of measurement

Tape mete Installed on the wall

4

Description

BMI(Body Mass Index)

Timepoint

Before and 2 months after supplementation

Method of measurement

Calculation:Weight (kg) / squared height (m)

5

Description

Waist circumference

Timepoint

Before and 2 months after supplementation

Method of measurement

Tape meter

6

Description

Hip circumference

Timepoint

Before and 2 months after supplementation

Method of measurement

Tape meter

7

Description

Waist to Hip ratio

Timepoint

Before and 2 months after supplementation

Method of measurement

Calculation

8

Description

Energy intake

Timepoint

Before supplementation

Method of measurement

24 hour recall

9

Description

Carbohydrate intake

Timepoint

Before supplementation

Method of measurement

24 hour recall

10

Description

protein intake

Timepoint

Before supplementation

Method of measurement

24 hour recall

11

Description

lipid intake

Timepoint

Before supplementation

Method of measurement

24 hour recall

12

Description

Cholesterol intake

Timepoint

befor supplementation

Method of measurement

24 hours recall

13

Description

fiber intake

Timepoint

befor supplementation

Method of measurement

24hours recall

14

Description

Saturated fatty acid intake

Timepoint

Before supplementation

Method of measurement

24 hour recall

15

Description

mono unSaturated fatty acid intake

Timepoint

Before supplementation

Method of measurement

24 hour recall

16

Description

polyunsaturated fatty acids intake

Timepoint

Before supplementation

Method of measurement

24 hour recall

Intervention groups

1

Description

People with pre-diabetes, a fasting blood sugar of 100 -125mg/ dL or a two-hour blood sugar between 140 to 199 mg/ dL - Range of BMI 25 to 34.9 Kg / m² - Age: 20 to 50 years. daily 3 g L-arginine (3 capsules containing 1 g L-arginine) was given every 8 hours for 8 weeks. At the end of the fourth and eighth weeks remaining capsules were counted, patients did not take their more than 10 percent of capsules, are excluded from the study. The subjects were told not to change diet and activity level.

Category

Treatment - Other

2

Description

People with pre-diabetes, a fasting blood sugar of 100 -125mg/ dL or a two-hour blood sugar between 140 to 199 mg/ dL - Range of BMI 25 to 34.9 Kg / m² - Age: 20 to 50 years. daily 3 g placebo(3 capsules containing 1 g Maltodextrin that was similar l-arginine) was given the same as the intervention group. The subjects were told not to change diet and activity level.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine Research Center, Shariati Hospital

Full name of responsible person

DR Mohajerani

Street address

Endocrine Research Center, Shariati Hospital, North Kargar Avenue,, Jalal Ale Ahmad Boulevard

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,Tehran University of Medical Sciences

Full name of responsible person

Dr Fotouhi

Street address

Vice chancellor for research,Tehran University of Medical Sciences,The 5th floor,Ghods Street, Keshavarz Blvd , Tehran

City

Tehran

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,Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Siavash Fazelian

Position

MSc Student of Nutrition

Other areas of specialty/work

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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

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Siavash Fazelian

Position

MSc Student of Nutrition

Other areas of specialty/work

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