

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 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

+98 21 6640 2095

##### 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 / m<sup>2</sup> - 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 / m<sup>2</sup> - 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

##### Street address

Nutrition and Biochemistry group,4th floor, Health Faculty, Poursina St, 16 Azar St, Keshavarz Blvd St, Tehran

##### City

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##### Postal code

##### Phone

+98 21 6640 2095

##### Fax

##### Email

siavash\_nut@yahoo.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Ahmad Saedi Some Olia

##### Position

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

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**Web page address****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****Street address**

Nutrition and Biochemistry group,4th floor, Health

**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*