

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### Effect of Vitamin C and Vitamin E Supplementation on Postprandial Oxidative Stress, Inflammatory Markers, Lipid Profile, Insulin and Blood Glucose Level of Type 2 Diabetic Patients

#### Protocol summary

##### Summary

Diabetes mellitus is one of the most wide spread endocrine disorders and among the most important developing health problems. In this study we evaluated the effect of vitamin E and vitamin C supplementation on postprandial glucose, insulin, lipid profiles, oxidative stress and inflammatory markers in type 2 diabetic patients. 45 patients with type 2 diabetes were randomly divided to 3 groups 1)treatment with vitamin E (400IU/day) 2)treatment with vitamin C (1000mg/d) and 3)placebo group. They were supplemented for 6 weeks, after that we measure biochemical parameters in fasting and postprandial state (after a breakfast that was containing 80g fat) the same as the first day of the study. Data analysis was carried out using one way ANOVA with  $P < 0.05$  being significant by SPSS software version 11.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138904073236N1**

Registration date: **2010-10-15, 1389/07/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2010-10-15, 1389/07/23

##### Registrant information

##### Name

Zohreh Mazloom

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1725 1008

##### Email address

zmazloom@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

shiraz university of medical sciences

##### Expected recruitment start date

2009-04-04, 1388/01/15

##### Expected recruitment end date

2009-08-21, 1388/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Vitamin C and Vitamin E Supplementation on Postprandial Oxidative Stress, Inflammatory Markers, Lipid Profile, Insulin and Blood Glucose Level of Type 2 Diabetic Patients

##### Public title

Effect of Vitamin C and Vitamin E Supplementation on Postprandial Oxidative Stress, Inflammatory Markers, Lipid Profile , Insulin and Blood Glucose Level of Type 2 Diabetic Patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

1- having diabetes 2- normal blood pressur 3- age between 25 to 65 4- having diabetes for maximum 15 years 5- nonsmoker, nonalcoholic 6- not taking vitamin and/or mineral supplement, insulin therapy, lipid

lowering, hormone replacement therapy, diuretics or  $\beta$ -blockers and aspirin 7- no history or clinical evidence of overt vascular disease, acute or chronic inflammatory disease and kidney stones 8- no history of radiation therapy

#### **Age**

From **25 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **45**

#### **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**

IRAN- Shiraz-Shiraz University of Medical Sciences

##### **City**

Shiraz

##### **Postal code**

#### **Approval date**

2009-07-16, 1388/04/25

#### **Ethics committee reference number**

88-4600

## **Health conditions studied**

### 1

#### **Description of health condition studied**

diabetes mellitus

#### **ICD-10 code**

E11

#### **ICD-10 code description**

Non-insulin-dependent diabetes mellitus

## **Primary outcomes**

### 1

#### **Description**

blood glucose fasting and postprandial

#### **Timepoint**

4 times, before and 6 weeks after intervention, fasting and postprandial

#### **Method of measurement**

Auto analyser

### 2

#### **Description**

Insulin Fasting and postprandial

#### **Timepoint**

4 times, before and after intervention, fasting and postprandial

#### **Method of measurement**

Radio Immune Assay

## **Secondary outcomes**

### 1

#### **Description**

lipid profile

#### **Timepoint**

before and 6 weeks after intervention, fasting and postprandial

#### **Method of measurement**

auto analyser

### 2

#### **Description**

Malondialdehyde

#### **Timepoint**

before and 6 weeks after intervention

#### **Method of measurement**

spectrophotometry

### 3

#### **Description**

high sensitive C-Reactive Protein

#### **Timepoint**

before and 6 weeks after intervention, fasting and postprandial

#### **Method of measurement**

ELIZA

### 4

#### **Description**

Interlukin-6

#### **Timepoint**

before and 6 weeks after intervention, fasting and postprandial

#### **Method of measurement**

Radio Immune Assay

## Intervention groups

1

### Description

placebo intake for 6 weeks

### Category

Placebo

2

### Description

vitamin C intake 1000mg/pday for 6 weeks

### Category

Treatment - Drugs

3

### Description

vitamin E intake;400IU/pday for 6 weeks

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Shahid Motahari clinic

#### Full name of responsible person

#### Street address

Shahid Motahari clinic

#### City

Shiraz

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shiraz Uuniversity Of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Hossein Dabaghmanesh

#### Street address

Shiraz University of Medical Sciences

#### City

Shiraz

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Shiraz Uuniversity 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

School of Health and Nutrition, Shiraz University of Medical Sciences

#### Full name of responsible person

Najmeh Hejazi

#### Position

Ph.D student of nutrition

#### Other areas of specialty/work

#### Street address

School of health and nutrition, Shiraz University of Medical Sciences

#### City

Shiraz

#### Postal code

#### Phone

+98 71 1720 6963

#### Fax

#### Email

n20hejazi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

School of health and nutrition, Shiraz University of Medical Sciences

#### Full name of responsible person

Dr. Zohreh Mazloom

#### Position

PHD of nutrition, Associate professor of nutrition department

#### Other areas of specialty/work

#### Street address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Najmeh Hejazi

**Position**

ph.D student

**Other areas of specialty/work**

**Street address**

Shiraz University of Medical Sciences, School of  
health and nutrition

**City**

Shiraz

**Postal code**

**Phone**

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**Fax**

**Email**

n20hejazi@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*