

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 β -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 Mediccal 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

School of health and nutrition, Shiraz University of Mediccal Sciences

City

Shiraz

Postal code

Phone

+98 71 1725 1005

Fax

Email

zmazloom@sums.ac.ir

Web page address

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

+98 71 1720 6963

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