Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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

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Iran (Islamic Republic of)

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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 intervation, 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
spectrophotometery

3

Description
high sensetive 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
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Shiraz University of Medical Sciences
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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
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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