Clinical Trial Protocol
Iranian Registry of Clinical Trials
15 Apr 2020

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 widespread 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 into 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
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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 pressure 3- age between 25 to 65 4- having diabetes for maximum 15 years 5- nonsmoker, non-alcoholic 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
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

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
Dr. Mohammad Hossein Dabaghmanesh
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Sponsors / Funding sources

1
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of Health and Nutrition, Shiraz 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
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

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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