Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of vitamin E supplementation on nitrosative and oxidative stress, serum zinc and metabolic status in type 2 diabetics

Protocol summary

Summary

Eighty persons from type 2 diabetic patients (women and men) will be selected at random. Ten cc of venous blood sample will be obtained from each patient at the beginning and end of study. Samples will be taken after 12-14 h fasting condition. For evaluation of dieting intake, 3 days food record will be gathered from each subject prior to the study, 4 weeks after beginning of study and at the end (after 8 weeks) of study. Intervention group will take vitamin E (400 mg) after eating launch for 8 weeks and control group also will take one placebo tablet for 8 weeks. Plasma levels of nitrite and nitrate, malondialdehyde, total antioxidant capacity, activity of paraoxonase-1 enzyme, HbA1c, insulin resistant (HOMA-IR), total cholesterol, LDL-C, HDL-C, TG, LDL/HDL, TC/HDL and serum zinc will be assessed in all of studied subjects before and after of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904263664N2**
Registration date: **2010-09-04, 1389/06/13**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2010-09-04, 1389/06/13

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research and Tabriz Nutritional Research center of Tabriz University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

Expected recruitment end date

2010-12-21, 1389/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin E supplementation on nitrosative and oxidative stress, serum zinc and metabolic status in type 2 diabetics

Public title

Effect of vitamin E supplementation on nitrosative and oxidative stress, serum zinc and metabolic status in type 2 diabetics

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: volunteer for participating in the study; diagnosis of diabetes at least 1 year prior to our examination; patients under treatment only with oral hypoglycemic agents at least for 6 months; BMI≤35; 30-60 years old. Exclusion criteria: pregnancy and lactating; liver, renal, heart, thyroid and inflammation disease; patients who are under treated with insulin, hypolipidemic and diuretic drugs, and who use fish oil or

garlic capsules and under treated with hormone; smoking; any change in dose of lowering blood glucose drugs which used by patients during the intervention; taking antioxidant supplements at least 3 months before the beginning of study.

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
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
The Research Ethics Committee of Tabriz University of Medical Sciences

Street address
Attare Neishaboori Avenue, Golgasht Street

City
Tabriz

Postal code

Approval date
2010-07-01, 1389/04/10

Ethics committee reference number
5/4/2528

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
metabolic status

Timepoint
before of intervention and 8 weeks after intervention

Method of measurement
blood sampling and analysing with related tests

2

Description
nitrosative stress

Timepoint
before of intervention and 8 weeks after intervention

Method of measurement
blood sampling and analysing with griess

3

Description
oxidative stress

Timepoint
before of intervention and 8 weeks after intervention

Method of measurement
blood sampling and analysing with spectrophotometry

4

Description
level of serum zinc

Timepoint
before of intervention and 8 weeks after intervention

Method of measurement
blood sampling and analysing with spectrophotometry

Secondary outcomes

1

Description
body mass index

Timepoint
before of intervention and 8 weeks after intervention

Method of measurement
measurement of weight and height

2

Description
energy intake

Timepoint
before of intervention, 4 and 8 weeks after intervention

Method of measurement
3 days food record

3

Description
protein intake

Timepoint

before of intervention, 4 and 8 weeks after intervention
Method of measurement
3 days food record

4

Description
carbohydrate intake
Timepoint
before of intervention, 4 and 8 weeks after intervention
Method of measurement
3 days food record

5

Description
fat intake
Timepoint
before of intervention, 4 and 8 weeks after intervention
Method of measurement
3 days food record

6

Description
intake of vitamin E
Timepoint
before of intervention, 4 and 8 weeks after intervention
Method of measurement
3 days food record

7

Description
intake of vitamin C
Timepoint
before of intervention, 4 and 8 weeks after intervention
Method of measurement
3 days food record

8

Description
intake of zinc
Timepoint
before of intervention, 4 and 8 weeks after intervention
Method of measurement
3 days food record

Intervention groups

1

Description
capsule of vitamin E, once a day, after launch
Category
Other

2

Description
capsule of placebo, once a day, after launch
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
specialized and subspecialized outpatient clinic of Tabriz university of medical sciences
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Maryam Rafraf
Street address
Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street
City
Tabriz
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, Tabriz University of Medical Sciences
Proportion provided by this source
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

2

Sponsor
Name of organization / entity
Nutritional Reseach Center of Tabriz University of Medical Sciences
Full name of responsible person
Alireza ostadrahimi
Street address
Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street
City
Tabriz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutritional Reseach Center of Tabriz University of Medical Sciences
Proportion provided by this source
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
Tabriz University of Medical Sciences
Full name of responsible person
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MS student in Nutrition
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Person responsible for updating data

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Full name of responsible person
Behnaz Bazyun
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Other areas of specialty/work
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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