

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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 \leq 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
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Person responsible for updating data

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Behnaz Bazyun
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Email
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