

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Effect of vitamin E supplementation on serum Hs-CRP and lipoprotein a in type 2 diabetics

Protocol summary

Summary

Aim of this study is to evaluate the effect of vitamin E supplementation on serum Hs-CRP and lipoprotein A in type 2 diabetes mellitus. Eighty persons from type 2 diabetic patients (women and men) will be selected randomly. 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 diet intake, 3 days food record will be gathered from each case 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 but control group will take one placebo tablet for 8 weeks. Serum levels of vitamin E, Hs-CRP and lipoprotein A will be assessed in all of studied cases before and after the intervention. Main inclusion criteria: patients under treatment only with oral hypoglycemic agents at least for 6 months; BMI \leq 35; 30-60 years old. Main exclusion criteria: pregnancy and lactating; patients who are under treated with insulin, 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.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104043664N4**

Registration date: **2011-04-16, 1390/01/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-16, 1390/01/27

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

rafrafm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutritional Reseach Center of Tabriz University of Medical Sciences, Vice-chancellor for research, 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 serum Hs-CRP and lipoprotein a in type 2 diabetics

Public title

Effect of vitamin E supplementation on serum Hs-CRP and lipoprotein a 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

2-3

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

level of serum vitamin E

Timepoint

before of intervention and 8 weeks after intervention

Method of measurement

blood sampling and analysing with HPLC

2

Description

level of serum Hs-CRP

Timepoint

before of intervention and 8 weeks after intervention

Method of measurement

blood sampling and analysing with Immunoturbidimetry

3

Description

level of serum lipoprotein a

Timepoint

before of intervention and 8 weeks after intervention

Method of measurement

blood sampling and analysing with imunoturbidometry

Secondary outcomes

empty

Intervention groups

1

Description

capsule of vitamin E, once a day, after launch

Category

Treatment - Drugs

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

Behnaz Bazyun

Street address

Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street

City

Tabriz

Sponsors / Funding sources**1****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***2****Sponsor****Name of organization / entity**

Vice-chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohamad Reza Rashidy

Street address

Tabriz University of Medical Sciences, Daneshgah 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***Person responsible for general inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Behnaz Bazyun

Position

MS student in Nutrition

Other areas of specialty/work**Street address**

Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street

City

Tabriz

Postal code**Phone**

+98 41 1666 0750

Fax**Email**

b_nutrition@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Behnaz Bazyun

Position

MS student in Nutrition

Other areas of specialty/work**Street address**

Health and Nutrition School, Attare Neishaboori Avenue, Golgasht Street

City

Tabriz

Postal code**Phone**

+98 41 1666 0750

Fax**Email**

b_nutrition@yahoo.com

Web page address**Person responsible for updating data****Contact**

Name of organization / entity

Tabriz University of Medical Sciences

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Health and Nutrition School, Attare Neishaboori
Avenue, Golgasht Street

City

Tabriz

Postal code**Phone**

+98 41 1666 0750

Fax**Email**

b_nutrition@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