

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

The Effect of vitamins and/or antioxidants on lipid profile and homocysteine in type 2 diabetes: A randomized controlled trial

Protocol summary

Summary

The objective of the study was to assess the effects of B-group vitamins and antioxidants vitamin C and E on lipid profiles and homocysteine levels in type 2 diabetic patients. In a block randomized, double-blind, placebo controlled clinical trial, 110 type 2 diabetic patients were assigned into five groups and received one of the following daily supplement for 2 months: group B: 10mg riboflavin, 10mg pyridoxine, 200µg cobalamin and 1000µg folic acid (n=23), group BE: same as group B and 100mg vitamin E(n=21), group BC: same as group B and 200mg vitamin C(n=22), group BCE: same as group BC and 100mg vitamin E(n=22), group P: Placebo(n=22). Fasting blood and urine samples were collected; body weight, height, waist circumference, hip circumference, dietary intake were also recorded at the beginning and at the end of 2 months trial and analyzed for cholesterol, triglyceride, HDL-c, LDL-c, apolipoproteins (apo) A1, vitamin E, folic acid, vitamin B12, vitamin C, and homocysteine.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102125805N1**

Registration date: **2011-04-10, 1390/01/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-04-10, 1390/01/21

Registrant information

Name

Parvaneh Yavari

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Supported by grant # 1038 from the Research
Undersecretary of Tehran University of Medical Sciences

Expected recruitment start date

2003-01-02, 1381/10/12

Expected recruitment end date

2004-01-01, 1382/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of vitamins and/or antioxidants on lipid profile
and homocysteine in type 2 diabetes: A randomized
controlled trial

Public title

The Effect of vitamins and/or antioxidants on lipid profile
and homocysteine in type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with fasting serum glucose
over 126 mg/dl and having diabetes for at least 1 year
with no abnormal hepatic or renal function, history of
myocardial infarction or taking vitamin supplements.
Exclusion Criteria: Unintention to continue the program

and Patients who didn't take 10% of their capsules or report any side effects.

Age

From **29 years** old to **68 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **110**

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

Ethics Committee of Tehran University of Medical Sciences

Street address

Vice-Cancellor for Reasearch, Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2002-11-17, 1381/08/26

Ethics committee reference number

130/5622

Health conditions studied

1

Description of health condition studied

Diabetes Type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Homocysteine

Timepoint

Before treatment and after 2 months intervention

Method of measurement

An enzyme-linked immunoassay

Secondary outcomes

1

Description

Triglyceride

Timepoint

Before treatment and after 2 months intervention

Method of measurement

Enzymatically

2

Description

HDL

Timepoint

Before treatment and after 2 months intervention

Method of measurement

Enzymatically

3

Description

LDL-c

Timepoint

Before treatment and after 2 months intervention

Method of measurement

Enzymatically

4

Description

Apo A1

Timepoint

Before treatment and after 2 months intervention

Method of measurement

Immunoturbidimetric method

5

Description

Total Cholesterol

Timepoint

Before treatment and after 2 months intervention

Method of measurement

Enzymatically

6

Description

Apo B

Timepoint

Before treatment and after 2 months intervention

Method of measurement

Intervention groups

1

Description

Ggroup B: 10mg riboflavin, 10mg pyridoxine, 200µg cobalamin and 1000µg folic acid

Category

Treatment - Drugs

2

Description

Group BE: same as group B and 100mg vitamin E

Category

Treatment - Drugs

3

Description

Group BC: same as group B and 200mg vitamin C

Category

Treatment - Drugs

4

Description

Group BCE: same as group BC and 100mg vitamin E

Category

Treatment - Drugs

5

Description

Group P: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The Endocrine Research and Metabolism Center of Shariati Hospital

Full name of responsible person

Parvaneh Yavari

Street address

Shariati Hospital, Jalal Al-e-Ahmad Highway

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research

Full name of responsible person

Fereydoun Siassi

Street address

Tehran University of Medical Sciences, School of Public Health, Department of Nutrition and BioChemistry, Enghelab St.,

City

Tehran

Grant name

معاونت پژوهشی دانشگاه علوم پزشکی تهران

Grant code / Reference number

1038

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research

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

Name of organization / entity

Tehran University Of Medical Sciences, School of Public Health, Department of nutrition and BioChemistry

Full name of responsible person

Parvaneh Yavari

Position

Assistant Professor

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