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

School of Nutritional Sciences and Dietetics, Tehran University of Medical Sciences

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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: Unitention 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

Immunoturbidimetric method

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
Tehran

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
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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