

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effects of omega-3 plus vitamin E, vitamin C plus zinc supplementation on serum lipids and lipoprotein profiles, inflammatory and oxidative stress biomarkers, and endothelial function in postmenopausal women with type 2 diabetes

Protocol summary

Summary

In this double blind randomized controlled clinical trial, we assessed the effects of omega-3 plus vitamin E and vitamin C plus zinc supplementation on serum lipids and lipoprotein profiles, inflammatory and oxidative stress biomarkers, as well as endothelial function in postmenopausal women with type 2 diabetes compared with the control group. In this 12-week trial, 75 postmenopausal women aged 50-65 years with type 2 diabetes participated from Iranian Diabetes Association. After obtaining the informed consent, subjects were assessed by dietary intake, anthropometric, clinical and medical history, and biochemical measurements. Subjects were randomly assigned to three groups to take 1) 1.8 g/day of omega-3 plus 400 mg/day vitamin E (group one), 2) five mg/day zinc plus 300 mg/day vitamin C (group two), 3) placebo (group three) for 12 weeks. During intervention period, individuals consumed their usual diet. They were assessed for cardiovascular risk factors, metabolic syndrome components, inflammation and oxidative stress biomarkers and endothelial function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804312214N1**
Registration date: **2009-09-01, 1388/06/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-09-01, 1388/06/10

Registrant information

Name

Mohammad Reza Mahmoodi

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1320 5056

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mr_mahmoodi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

National Nutrition and Food Technology Research Institute and Vice chancellor for Research of Kerman University of Medical Sciences

Expected recruitment start date

2008-03-19, 1386/12/29

Expected recruitment end date

2009-05-18, 1388/02/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of omega-3 plus vitamin E, vitamin C plus zinc supplementation on serum lipids and lipoprotein profiles, inflammatory and oxidative stress biomarkers, and endothelial function in postmenopausal women with type 2 diabetes

Public title

The effects of omega-3 plus vitamin E, vitamin C plus

zinc supplementation on serum lipids and lipoprotein profiles, inflammatory and oxidative stress biomarkers, and endothelial function in postmenopausal women with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: willingness to participate in the study and sign the informed consent, postmenopausal women with age of 50 to 65 years, presence of type 2 diabetes at least for one year (according to the American Diabetes Association criteria), non-insulin therapy, receiving either diet therapy or diet therapy with combination of oral anti-diabetic medications, no history of myocardial infarction, stroke, cardiovascular disease, active cancer, liver, kidney and thyroid dysfunction, or infectious diseases, Exclusion criteria: changing in dose of medications such as oral anti-diabetic, anti-lipidemic and anti-hypertensive drugs, occurrence of myocardial infarction, stroke, active cancer, liver, kidney, thyroid dysfunction, or infectious diseases, changing in drug regimen or insulin therapy, smoking, consumption of anti-oxidant vitamin supplements and fish oil capsules, non-steroidal anti inflammatory drugs, corticosteroids, anti-platelets or anti-coagulation drugs three months prior to study, hormone replacement therapy.

Age

From **50 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Nutrition and Food Technology Research Institute

Street address

National Nutrition and Food Technology Research

Institute, West Arghavan, Shaheed Farahzadi Blvd.
Shahrak-E-Gharb Tehran, Iran. <http://www.nnftri.ac.ir>
P.O. Box: 19395-4741

City

Tehran

Postal code

1981619573

Approval date

2008-12-01, 1387/09/11

Ethics committee reference number

25/47/5830

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

Fasting insulin serum

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

2

Description

Fasting blood glucose

Timepoint

Baseline and after 12 weeks

Method of measurement

Glucose oxidase, Enzymatic colorimetric

3

Description

HbA1C (Glycosilated hemoglobin)

Timepoint

Baseline and after 12 weeks

Method of measurement

Ion exchange method

4

Description

Insulin resistance

Timepoint

Baseline and after 12 weeks

Method of measurement

HOMA-IR calculation

5

Description

Serum triglyceride

Timepoint

Baseline and after 12 weeks

Method of measurement

Glycerol phosphate oxidase, Enzymatic colorimetric

6

Description

Total cholesterol

Timepoint

Baseline and after 12 weeks

Method of measurement

Enzymatic photometric

7

Description

HDL-cholesterol

Timepoint

Baseline and after 12 weeks

Method of measurement

Enzymatic photometric

8

Description

LDL-cholesterol

Timepoint

Baseline and after 12 weeks

Method of measurement

Friedewald formula

9

Description

Apo lipoprotein B100

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

10

Description

hsC-Reactive Protein

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

11

Description

Tumor Necrosis Factor- α

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

12

Description

Interleukin-6

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

13

Description

Fibrinogen

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

14

Description

tissue-plasminogen activator (t-PA)

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

15

Description

Plasminogen activator inhibitor-1 (PAI-1)

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

16

Description

Ox-LDL

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

17

Description

Malonedialdehyde (MDA)

Timepoint

Baseline and after 12 weeks

Method of measurement

TBARS, Chemical colorimetric

18

Description

Total antioxidant capacity (TAC)

Timepoint

Baseline and after 12 weeks

Method of measurement

Colorimetric

19

Description

SOD

Timepoint

Baseline and after 12 weeks

Method of measurement

Kit Jaica

20

Description

GPX

Timepoint

Baseline and after 12 weeks

Method of measurement

Kit Jaica

21

Description

Arylesterase / Paraoxonase

Timepoint

Baseline and after 12 weeks

Method of measurement

Enzymatic colorimetric

22

Description

E-Selectin

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

23

Description

sICAM-1

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

24

Description

sVCAM-1

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

25

Description

Systolic / Diastolic blood pressure

Timepoint

Baseline and after 12 weeks

Method of measurement

Mercurial Sphygmomanometer ALP K2

26

Description

Apo lipoprotein A1

Timepoint

Baseline and after 12 weeks

Method of measurement

ELISA assay

Secondary outcomes

1

Description

Medical events with special focus on cardiovascular

Timepoint

Baseline and every week until the end of intervention

Method of measurement

She was asked for any medical and activity conditions by investigator week to week or any time the patients want to call first executor and research doctor (councillor)

2

Description

Clinical and emotional improvement

Timepoint

Baseline and every week until the end of intervention

Method of measurement

She was asked for any medical and activity conditions by investigator week to week or any time the patients want to call first executor and research doctor (councillor)

Intervention groups

1

Description

1.8 g Omega-3 plus 400 mg vitamin E

Category

Treatment - Drugs

2

Description

300 mg Vitamin C plus 5 mg zinc

Category

Treatment - Drugs

3

Description

Placebo capsule containing 500 mg canola oil

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Diabetes Society

Full name of responsible person

Asadollah Rajab (MD)

Street address

Iranian Diabetes Society, No 46. Ramin Malakuty Avenue, Patris Lomomba Avenue, Sattar Khan Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Nutrition and Food Technology Research Institute

Full name of responsible person

Dr Esmat Nasserri (Deputy of Research)

Street address

National Nutrition and Food Technology Research Institute, West Arghavan, Shaheed Farahzadi Blvd. Shahrak-E-Gharb

City

Tehran

Grant name

پروژه تحقیقاتی

Grant code / Reference number

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

Yes

Title of funding source

National Nutrition and Food Technology Research Institute

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 of Kerman University of Medical Sciences.

Full name of responsible person

Professor Hamid Najafi pour

Street address

Vice chancellor for Research of Kerman University of Medical Sciences. Jihad Blvd. Ebn Sina Avenue

City

Kerman

Grant name

پروژه تحقیقاتی

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for Research of Kerman 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

3

Sponsor

Name of organization / entity

Minami Nutrition Co.

Full name of responsible person

Jo Wyckmans

Street address

University Business Centre Antwerp, Drie Eikenstraat 661, 2650

City

Edegern

Grant name

پروژه تحقیقاتی

Grant code / Reference number

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

Yes

Title of funding source

Minami Nutrition Co.

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

4

Sponsor

Name of organization / entity

PouraTeb Medical & Pharmaceutical Company

Full name of responsible person

Beheshti

Street address

Africa Street, higher than Mirdamad, next to Park Saba, East Pirouzi Alley, No.6

City

Tehran

Grant name

پروژه تحقیقاتی

Grant code / Reference number

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

Yes

Title of funding source

PouraTeb Medical & Pharmaceutical Company

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

5

Sponsor

Name of organization / entity

HakimanTeb Pharmaceutical Company

Full name of responsible person

Javad Jafari

Street address

Mohseni Square, Shah Nazari Street, Nahid Tower,
2nd Floor

City

Tehran

Grant name

پروژه تحقیقاتی

Grant code / Reference number

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

Yes

Title of funding source

HakimanTeb Pharmaceutical Company

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

Department of Nutrition, School of Health

Full name of responsible person

Mohammad Reza Mahmoodi

Position

PhD

Other areas of specialty/work

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Position

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Full name of responsible person

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Email

mr_mahmoodi@kmu.ac.ir , mahmoodimr@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