

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Clinical trial of the effect of vitamin E supplementation compared with the placebo on lipid profiles in patients with diabetic nephropathy

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of vitamin E supplementation on lipid profiles in patients with diabetic nephropathy.

Design

Randomized, double-blind, placebo-controlled clinical trial, phase 3, 54 patients

Settings and conduct

54 patients with diabetic nephropathy of eligible and referred to Shahid Beheshti Clinic, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Patients with diabetic nephropathy with a proteinuria level >0.3 g/24 h, with or without elevation of serum creatinine levels and aged 40 to 85 years will be included in this study. Exclusion criteria: Vitamin E supplementation within 3 months, pregnant women, chronic liver disease.

Intervention groups

Patients will be assigned to receive either vitamin E (intervention group: n=27) or placebo (control group: n=27).

Main outcome variables

Outcomes: Lipid profiles (primary outcomes), biomarkers of oxidative stress (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201706055623N117**

Registration date: **2017-06-11, 1396/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-22, 1398/06/31**

Update count: **1**

Registration date

2017-06-11, 1396/03/21

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 36 1534 3570

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asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2017-05-18, 1396/02/28

Expected recruitment end date

2017-06-18, 1396/03/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of vitamin E supplementation compared with the placebo on lipid profiles in patients with diabetic nephropathy

Public title

Effect of supplementation in treatment of patients with diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with diabetic nephropathy Aged 40 to 85 years

Exclusion criteria:

Vitamin E supplementation within 3 months Pregnant women Chronic liver disease

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI and age. Then, participants in each block will be randomly allocated into two treatment groups to take either vitamin E supplement or placebo. Randomization will be done by the use of Stat Trek software.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Shahid Beheshti Clinic in Kashan who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2017-05-17, 1396/02/27

Ethics committee reference number

IR.Kaums.REC.1396.25

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

N08.3

ICD-10 code description

Glomerular disorders in diabetes mellitus (E10-E14 with common fourth character .2+)

Primary outcomes

1

Description

Total cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

2

Description

Triglyceride

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

3

Description

HDL-cholesterol

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

4

Description

LDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

VLDL

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Secondary outcomes

1

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Total glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Nitric oxide

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

4

Description

FPG

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

5

Description

HbA1c

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Glycomat kit

Intervention groups

1

Description

Intervention group: Vitamin E capsule, 800 mg (Zahravi, Tabriz, Iran), once a day, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), once a day, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Clinic

Full name of responsible person

Zatollah Asemi

Street address

Ghotbe Ravandi Boulevard, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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, Kashan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Zatollah Asemi
Position
PhD of Nutrition
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to

make this available
Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available