

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

A survey of effect of vitamin E supplement on advanced glycation end products, oxidative stress and inflammatory markers in diabetic nephropathy patients

Protocol summary

Study aim

The aim of this study is to determine the effects of vitamin E supplements on advanced glycation end products, oxidative stress and inflammatory markers in diabetic nephropathy patients .

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial

Settings and conduct

Patients with diabetic nephropathy eligible and referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran in the study will be selected.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with diabetic nephropathy, aged 40 to 85 years with a proteinuria level of > 0.3 g / 24 h, with or without serum creatinine level. The exclusion criteria will be the consumption of vitamin E supplements within 3 months, patients with uncontrolled diabetes, pregnant women, and those with liver or inflammatory diseases.

Intervention groups

The volunteers divided into two groups 30 patients. one group received per day of vitamin E 1200 IU and another group received placebo capsules per day for 3 months.

Main outcome variables

Serum levels of vitamin E, an advanced glycation end products (AGE), inflammatory factors such as matrix metalloproteinase 9 and 2 (MMP9-2) , TNF_alpha , malondialdehyde (MDA) oxidative stress factor , HOMA-IR and proteinuria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122020374N1**

Registration date: **2015-05-06, 1394/02/16**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-24, 1398/07/02**

Update count: **1**

Registration date

2015-05-06, 1394/02/16

Registrant information

Name

Esmat Aghadavod

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences and Health Services

Expected recruitment start date

2015-03-05, 1393/12/14

Expected recruitment end date

2015-05-25, 1394/03/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A survey of effect of vitamin E supplement on advanced glycation end products, oxidative stress and inflammatory markers in diabetic nephropathy patients

Public title

The effect of vitamin E on nephropathy complications of diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with diabetic nephropathy Aged 40 to 85 years Proteinuria level > 0.3 g/24 h with or without circulating levels of serum creatinine.

Exclusion criteria:

The consumption of vitamin E supplements within 3 months Patients with uncontrolled diabetes, Pregnant women Those with liver or inflammatory diseases

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: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after stratification for pre-intervention BMI and age, subjects will be randomly divided into two groups to take either vitamin E supplements (n = 30) or placebo (n = 30). Randomization will be done by the use of computer-generated random numbers.

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, who is not involved in the trial and not aware of random sequence

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee kashan university of medical sciences and health services

Street address

kashan university of medical sciences and health services, Ravand road

City

kashan

Province

Isfahan

Postal code

81151-87159

Approval date

2015-03-04, 1393/12/13

Ethics committee reference number

29/5/1/5981 /پ

Health conditions studied

1

Description of health condition studied

diabetic nephropathy

ICD-10 code

E11.2

ICD-10 code description

non-insulin-dependent diabetic melitus with renal complications

Primary outcomes

1

Description

Tumour necrosis factor-alpha (TNF-alpha)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed.by an enzyme-linking immunosorbent assay (ELISA) kit. pg/ml

2

Description

Matrix metalloproteinases 9(MMP9)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by ELISA kit. ng/ml

3

Description

matix metalloproteinases 2(MMP2)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed .by ELISA kit. ng/ml

Secondary outcomes

1

Description

advanced glycation end products (AGEs)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed .By fluorescence method

2

Description

Vitamin E

Timepoint

Before and three months after intervention

Method of measurement

Enzymatic kits

3

Description

Creatinine

Timepoint

Before and three months after intervention

Method of measurement

Enzymatic kits

4

Description

Blood urea nitrogen

Timepoint

Before and three months after intervention

Method of measurement

Enzymatic kits

5

Description

Total protein

Timepoint

Before and three months after intervention

Method of measurement

Enzymatic kits

6

Description

Fasting plasma glucose

Timepoint

Before and three months after intervention

Method of measurement

Enzymatic kits

7

Description

Insulin

Timepoint

Before and three months after intervention

Method of measurement

ELISA kits

8

Description

Malondialdehyde

Timepoint

Before and three months after intervention

Method of measurement

Spectrophotometry

9

Description

Insulin resistance

Timepoint

Before and three months after intervention

Method of measurement

Calculation using HOMA formula

Intervention groups

1

Description

Intervention:daily received 1200 IU vitamin E for three months

Category

Treatment - Drugs

2

Description

control: daily received placebo for three months

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Kidney Sections of Beheshti Hospital

Full name of responsible person

Dr.Alireza Soleimani

Street address

Beheshti Hospital ,Ravand road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Gholam Ali Hamidi

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research@kaums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

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

Dr.Esmat Aghadavod Jolfaie

Position

PhD Clinical Biochemistry/ Academic staff member of the Department of Clinical Biochemistry

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Web page address**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