Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 capsulles 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
Isfehan
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 metalloproteinas 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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81151-87159
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+98 31 5562 0608
Email
beheshti@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Dr.Gholam Ali Hamidi

Street address
Vice chancellor for research, Kashan University of Medical Sciences ,Ravand road

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Province
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81151-87159

Phone
+98 31 5554 2999

Email
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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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