

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effects of selenium supplementation on advanced glycation end products, biomarkers of inflammatory and oxidative stress in diabetic nephropathy patients in comparison with placebo: a randomized double-blinded controlled clinical trial

Protocol summary

Study aim

The aim of this study is to determine the effects of selenium supplementation on advanced glycation end products (AGEs), inflammatory factor and biomarkers of oxidative stress in diabetic nephropathy patients.

Design

Randomized double-blinded controlled clinical trial. Blinding is carried out for patients and researchers and randomization is done by random table numbers. Patients will be assigned to receive either selenium (intervention group: n=30) or placebo (control group: n=30).

Settings and conduct

Among patients with diabetic nephropathy referred to the Shahid Beheshti Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention.

Participants/Inclusion and exclusion criteria

Patients with diabetic nephropathy aged 40 to 85 years will be included in this study. Inclusion Criteria: Patients with diabetic nephropathy with a proteinuria level of >0.3 g/24 hours, with or without circulating levels of serum creatinine. Exclusion criteria: The consuming selenium supplements within 3 months before beginning of the study, history of hospital admission within 3 months, bacteriuria, haematuria, urinary tract infection, patients with uncontrolled diabetes, pregnant women and those with liver or inflammatory diseases.

Intervention groups

Patients will be assigned to receive either selenium (intervention group: n=30) or placebo (control group: n=30).

Main outcome variables

Outcomes: Markers of insulin, insulin resistance and high-sensitivity C-reactive Protein (primary outcomes) and other metabolic profiles (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060622562N1**

Registration date: **2015-08-02, 1394/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **1**

Registration date

2015-08-02, 1394/05/11

Registrant information

Name

Fereshteh Bahmani

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

fbahmani@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kashan University of Medical Sciences

Expected recruitment start date

2015-07-11, 1394/04/20

Expected recruitment end date

2015-08-11, 1394/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of selenium supplementation on advanced glycation end products, biomarkers of inflammatory and oxidative stress in diabetic nephropathy patients in comparison with placebo: a randomized double-blinded controlled clinical trial

Public title

The effect of selenium on nephropathy complications of diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diabetic nephropathy with a proteinuria level of >0.3 g/24 hours With or without circulating levels of serum creatinine

Exclusion criteria:

The consumption of selenium supplements within 3 months before beginning of the study Patients with uncontrolled diabetes Pregnant women Liver diseases Inflammatory diseases Bacteriuria Haematuria Urinary tract infection History of hospital admission within 3 months

AgeFrom **40 years** old to **85 years** old**Gender**

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample sizeTarget 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 selenium 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 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 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

2015-05-24, 1394/03/03

Ethics committee reference number

IR.KAUMS.REC.1394.22

Health conditions studied**1****Description of health condition studied**

diabetic nephropathy

ICD-10 code

E11.2

ICD-10 code description

non-insulin-dependent diabetes mellitus with renal complications

Primary outcomes**1****Description**

serum insulin

Timepoint

Before and three months after intervention

Method of measurement

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

2**Description**

Inflammatory factor hs-CRP

Timepoint

Before and three months after intervention

Method of measurement

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

3

Description

Insulin resistance

Timepoint

Before and three months after intervention

Method of measurement

Calculation using HOMA formula

Secondary outcomes

1

Description

Matrix metalloproteinases 2 (MMP2)

Timepoint

Before and three months after intervention

Method of measurement

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

2

Description

Protein carbonyl

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by colorimetric method

3

Description

Tumor growth factor-beta (TGF-b)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by an enzyme-linking immunosorbent

4

Description

Glutathione peroxidase (GPx)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by an enzyme-linking immunosorbent

5

Description

Malondialdehyde (MAD)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by spectrophotometric

method.μmol/L

6

Description

Advanced glycation end products (AGEs)

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by fluorescence method

7

Description

Total Glutathione

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by spectrophotometric method.μmol

8

Description

Plasma total antioxidant

Timepoint

Before and three months after intervention

Method of measurement

In serum sample will assessed by colorimetric method

Intervention groups

1

Description

Intervention: received one capsule of 200 μg selenium, daily for three months

Category

Treatment - Other

2

Description

control: received one capsule of placebo daily 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

Ghotbe Ravandi Boulevard, Kashan

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Province

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Postal code
8115187159
Phone
+98 31 5546 3378
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soleimani_a@kaums.ac.ir

2

Recruitment center

Name of recruitment center
Dialysis Department of Akhavan Hospital
Full name of responsible person
Dr. Alireza Soleimani
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Abazar Street
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soleimani_a@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Kashan University of Medical Sciences
Full name of responsible person
Dr. Gholam Ali Hamidi
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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

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
Dr. Fereshteh Bahmani
Position
PhD Clinical Biochemistry /Academic staff member of the Department of Clinical Biochemistry
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of medical Sciences

Full name of responsible person

Dr. Fereshteh Bahmani

Position

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

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Medical faculty, Kashan University of medical Sciences, Ravand road, Kashan,Iran

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Province

Isfahan

Postal code

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