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 in 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
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Iran (Islamic Republic of)
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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
Age
From **40 years** old to **85 years** old
Gender
Both

Phase
2
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 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
Isfehan
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 cholorimetric 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

Gluthatione 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 Gluthatione

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 cholorimetric 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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Isfehan
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8115187159
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2

Recruitment center
Name of recruitment center
Dialysis Department of Akhavan Hospital
Full name of responsible person
Dr.Alireza Soleimani
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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
Dr.Gholam Ali 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
Dr. Fereshteh Bahmani
Position
PhD Clinical Biochemistry /Academic staff member of the Department of Clinical Biochemistry
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Person responsible for updating data

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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

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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