Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of the effect of selenium supplementation on gene expression levels associated with insulin, lipid and inflammatory metabolism in diabetic hemodialysis patients

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of selenium supplementation on gene expression related to insulin, lipid, and inflammation in diabetic hemodialysis patients

Design

Study design: Randomized double-blind placebo-controlled trial. Patients will be assigned into two groups to receive selenium supplement (n=20) or placebo (n=20).

Settings and conduct

Among Diabetic hemodialysis patients referred to Akhavan Clinic affiliated to Kashan University of Medical Sciences, 40 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diabetic hemodialysis patients aged 45 to 75 years. Exclusion criteria: patients taking antioxidant and/or anti-inflammatory supplements within 3 months prior to intervention; patients with infectious diseases; patients with malignant diseases.

Intervention groups

Intervention group: Selenium supplements (Nature, California, USA), 200 µg, daily, for 24 weeks orally. Control group: placebo (Barij Essence, Kashan, Iran), daily, for 24 weeks orally.

Main outcome variables

Outcomes: Expressed levels of PPAR-γ gene (primary outcome) and gene expression related to inflammation and lipid (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N62**
Registration date: **2019-08-03, 1398/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-03, 1398/05/12**
Update count: **0**

Registration date

2019-08-03, 1398/05/12

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-09, 1398/04/18

Expected recruitment end date

2019-08-09, 1398/05/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of selenium supplementation

on gene expression levels associated with insulin, lipid and inflammatory metabolism in diabetic hemodialysis patients

Public title
Selenium supplementation in the treatment of hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diabetic hemodialysis patients aged 45 to 75 years.
Exclusion criteria:
Patients taking antioxidant and/or anti-inflammatory supplements within 3 months prior to intervention Patients with infectious diseases Patients with malignant diseases
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 40 by SPSS software and participants will be randomly assigned into each intervention group by their numbers. The block randomization technique with 1:1 ratio will be used to achieve balanced group sizes.
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 Akhavan clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of supplements. Supplements and placebos are in the same packaging at the Barij Essence pharmaceutical company. Only the code is written on the packages. Patients and researcher do not know the type of intervention and after analyzing the data, packet codes are decoded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islamic Azad University-Yazd Branch
Street address
Shahid Gomnam Boulevard, Yazd
City
Yazd
Province
Yazd
Postal code
8915813135
Approval date
2019-07-08, 1398/04/17
Ethics committee reference number
IR.IAU.YAZD.REC.1398.022

Health conditions studied

1

Description of health condition studied
Hemodialysis
ICD-10 code
N18.6
ICD-10 code description
End stage renal disease

Primary outcomes

1

Description
Expressed levels of PPAR-γ gene
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
RT-PCR

Secondary outcomes

1

Description
Expressed levels of TNF gene
Timepoint
At the beginning of the study and after 24 weeks of intervention
Method of measurement
RT-PCR

2

Description
Expressed levels of VEGF gene
Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

RT-PCR

3

Description

Expressed levels of TGF-β gene

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

RT-PCR

4

Description

Expressed levels of IL-1 gene

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

RT-PCR

5

Description

Expressed levels of IL-8 gene

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

RT-PCR

6

Description

Expressed levels of LDL-ox gene

Timepoint

At the beginning of the study and after 24 weeks of intervention

Method of measurement

RT-PCR

Intervention groups

1

Description

Intervention group: Selenium supplements (Nature, California, USA), 200 µg, daily, for 24 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Placebo (Barij Essence, Kashan, Iran), daily, for 24 weeks orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan Clinic

Full name of responsible person

Zatollah Asemi

Street address

Shahid Rajaee Avenue, Kashan

City

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Isfehan

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1771844351

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Navid Nasiri Zadeh

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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

Islamic Azad University

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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Ghotbe Ravandi Boulevard, Kashan
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Person responsible for scientific inquiries

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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