

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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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ostadmohammadi-vr@kaums.ac.ir

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 Gornam 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 μ g, 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

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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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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