

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of selenium supplementation on lipid profile, anemia and inflammation indices in patients undergoing peritoneal dialysis: A placebo-controlled clinical trial

Protocol summary

Study aim

The aim of this study was to evaluate the effect of selenium supplementation on lipid profile, anemia and inflammation parameters in patients undergoing peritoneal dialysis.

Design

A concealed, randomized, blinded, sham-controlled clinical trial with a parallel-group design of 90 patients, block randomization was used for randomization

Settings and conduct

Individuals who meet the inclusion criteria will be randomly assigned to the intervention and control groups. Demographic and clinical characteristics of patients will be recorded. Patients in the intervention group will receive 200 micrograms of selenium tablets daily for 3 months. Participants in the control group will receive a placebo. At the end of 3 months, serum selenium levels and lipid profiles and indicators related to anemia and inflammation are measured and recorded again. Finally, using statistical tests, the average of the measured tests will be compared between the two groups. Researchers involved in sampling and blinded patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients under peritoneal dialysis over 18 years old; At least three months have passed since the first dialysis. Be satisfied with the study. Exclusion criteria: Having active hepatitis. Normal serum selenium levels. Taking steroidal and non-steroidal anti-inflammatory drugs within two months before the start of the study. Take selenium supplements within two months of starting the study. Insufficient incompatibility to consume the product

Intervention groups

The intervention group was treated with 200 micrograms of selenium tablets daily and the control group was treated daily with placebo for 3 months.

Main outcome variables

Serum selenium levels and fat profiles and indicators associated with anemia and inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160713028901N4**

Registration date: **2020-11-08, 1399/08/18**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-08, 1399/08/18**

Update count: **0**

Registration date

2020-11-08, 1399/08/18

Registrant information

Name

Shirinsadat Badri

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3792 7068

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-06-22, 1400/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of selenium supplementation on lipid profile, anemia and inflammation indices in patients undergoing peritoneal dialysis: A placebo-controlled clinical trial

Public title

The effect of selenium supplementation on lipid profile, anemia and inflammation indices

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients undergoing peritoneal dialysis over 18 years of age At least three months have passed since the first dialysis session Satisfied with the study

Exclusion criteria:

Having active hepatitis (according to several studies, selenium levels decrease in patients with hepatitis B and C) Normal serum selenium levels Taking steroidal and non-steroidal anti-inflammatory drugs within two months before the start of the study Take selenium supplements within two months of starting the study Insufficient incompatibility to consume the product

AgeFrom **18 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant

Sample sizeTarget sample size: **90****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, the randomization of samples will be based on the block randomization method. Information such as the number of treatment groups (the two main intervention groups for example A and placebo for example B), the size of the blocks (a multiple of the number of groups that will be selected in this study to reduce the complexity of size 4 work) and the total number of patients (sample size 90 (For example, available at

<https://www.sealedenvelope.com/simple-randomiser/v1/lits>) and according to the codes with the final analysis (including the number of specified groups 4). A code will be assigned to each patient entering the study, and the type of group to receive medication or placebo will be determined. Blocking is usually used to balance the number of samples assigned to each of the groups studied. In this method, equal blocking will be used. In this way, the samples are randomized as much as possible in the two groups. At the end of the sampling, the code of each patient is opened and matched with the

software output, and as far as possible, the data collector and the intervener try to be informed of the drug code information only after analyzing the data.

Blinding (investigator's opinion)

Double blinded

Blinding description

The placebo will be prepared in Isfahan School of Pharmacy or Amin Pharmaceutical Company (service purchase). The placebo capsule has a similar appearance and is made from common expanses in the production and filling of pharmaceutical supplements; The drug and placebo are placed in the same package by the researcher so that the blinding method can be performed well. Then a small number of placebo and supplement products are provided to the patient, assuming that the entire course is completed with a daily dose and a specific code. The information in this special code on drug packages is only available to the main executor of the project who is not involved in the sampling, and the rest of the project partners do not know if the relevant code is for the drug or placebo. Thus, sampling will be done by blind method.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan university of medical sciences

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Hezar-Jerib

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Postal code

81746-73461

Approval date

2020-10-03, 1399/07/12

Ethics committee reference number

IR.MUI.MED.REC.1399.574

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

Peritoneal Dialysis

ICD-10 code

N 18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Serum selenium levels

Timepoint

Before the start and after the end of 3 months

Method of measurement

Serum selenium level of patients by atomic electron normal absorption method with graphite furnace using unicam929-uk device made by variant company in USA

2

Description

Lipid profiles (including total cholesterol, LDL, HDL, and TG)

Timepoint

Before the start and after the end of 3 months

Method of measurement

By standard laboratory methods

3

Description

Indicators associated with anemia

Timepoint

Before the start and after the end of 3 months

Method of measurement

By standard laboratory methods

4

Description

Inflammation

Timepoint

Before the start and after the end of 3 months

Method of measurement

By standard laboratory methods

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treated with 200 micrograms alpha brand selenium tablets, every afternoon for 3 consecutive months

Category

Treatment - Drugs

2

Description

Control group: Treated with placebo tablets daily, for 3 consecutive months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra University Hospital

Full name of responsible person

Shirinsadat Badri

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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjoi Javanmard

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Shirinsadat Badri

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available