Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Nov 2026

Determining the effect of selenium supplement on inflammatory, oxidative and nutritional markers in hemodialysis patients

Protocol summary

Summary

The aim of this study was to assess the effects of selenium supplement on inflammatory, oxidative and nutritional markers in hemodialysis patients. The study was done on 80 patients undergoing hemodialysis. We included the ones who were being dialyzed at least twice a week and had undergone dialysis at least for 3 months. Subjects were excluded if they were prescribed any multivitamins or immunosuppressive drugs or if they had been hospitalized in the previous month; we also excluded the ones who were pregnant or had active infections. After taking written consent, blood samples were taken to measure their lipoprotein, malondialdehyde, interleukin-6, c-reactive protein, calcium, phosphorus and parathyroid hormone, then patients in control group received a placebo capsule a day (was made of starch) during the 3-month of trial period and patients in the experimental group received 200 microgram selenium in the form of selenium yeast (a capsule a day) for three months. Blood samples were taken again after 3 months and biochemical measurements were done. Every patient filled the SF-36 questionnaire and 3-day dietary recall and their weights were recorded at the beginning and after 3 months. Assessing SGA and appetite status were also done for every patient by interviewing at the beginning and at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812083446N1**
Registration date: **2009-04-04, 1388/01/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-04-04, 1388/01/15

Registrant information

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Recruitment status

Recruitment complete

Funding source

Shiraz university of medical sciences,transplantation research center

Expected recruitment start date

2009-04-04, 1388/01/15

Expected recruitment end date

2009-07-06, 1388/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of selenium supplement on inflammatory, oxidative and nutritional markers in hemodialysis patients

Public title

Determining the effect of selenium supplement on inflammatory, oxidative and nutritional markers in hemodialysis patients in shiraz medical university

hemodialysis centers

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being on dialysis at least 2-3 sessions per week for 3 months, age range of 17-85 years. Exclusion criteria: being admitted in hospital during last month, having active infection, using multivitamins or immunosupressive drugs, being pregnant.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz university of medical sciences

Street address

Shiraz university of medical sciences

City

Shiraz

Postal code

Approval date

2009-09-29, 1388/07/07

Ethics committee reference number

88-4747

Health conditions studied

1

Description of health condition studied

End stage renal disease

ICD-10 code

N18.0

ICD-10 code description

End-stage renal disease

Primary outcomes

1

Description

malondialdehyde (oxidative stress)

Timepoint

2 times with 3 months interval

Method of measurement

spectrophotometery

Secondary outcomes

1

Description

subjective global assesment

Timepoint

2 times with 3 months interval

Method of measurement

questinnaire

2

Description

serum albumin

Timepoint

2 times with 3 months interval

Method of measurement

ELISA kit

3

Description

Interleukin-6

Timepoint

2 times with 3 months interval

Method of measurement

ELISA kit

4

Description

c-reactive proteins

Timepoint

2 times with 3 months interval

Method of measurement

ELISA kit

5

Description

food intake

Timepoint

2 times with 3 months interval

Method of measurement

questinnaire

Intervention groups

1

Description
Treatment group:200 micrograms of selenium supplement for 3 months
Category
Treatment - Drugs

2

Description
Control group: an starch capsule for 3 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi hospital and Namazi hospital
Full name of responsible person
Street address
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz university of medical sciences
Full name of responsible person
Dr.Mohammad Hassan Dabbaghmanesh
Street address
Shiraz university of medical sciences
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz university of medical sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty