

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Determining the effect of selenium supplement on serum adiponectin and homocystein levels and malnutrition-inflammation complex syndrome (MICS) in hemodialysis patients

Protocol summary

Summary

In order to evaluate the effect of selenium supplementation on serum adiponectin and homocystein concentrations and markers of malnutrition-inflammation complex syndrome (MICS) in hemodialysis patients, a randomized double blind clinical trial was done. Eighty hemodialysis patients with the age range of 17-85 years who were on dialysis at least 2 times per week without any infection or hospitalization were divided into two groups of control and experimental and they took placebo (containing yeast) and selenium (200 microgram) for 3 months respectively. Before and after the intervention, in all patients, serum concentrations of adiponectin, homocystein, ferritin, transferin, albumin and CRP were measured by ELISA kits and each patient had 3-day food intake and SF-36 quality life questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812043408N1**

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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Name of organization / entity

Shiraz University of Medical Sciences, Nutrition Department

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Iran (Islamic Republic of)

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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 serum adiponectin and homocystein levels and malnutrition-inflammation complex syndrome (MICS) in hemodialysis patients

Public title

Effect of selenium on malnutrition- inflammation complex syndrome (MICS) in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: hemodialysis patients who are on dialysis at least two times per week and in the age range of 17-85 years. Exclusion Criteria: having infection, hospitalization, taking multivitamins, antibiotics or

immunosuppressants, being pregnant.

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

Gender
Both

Phase
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)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
ClinicalTrials.gov

Secondary trial Id
NCT01150786

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand street

City
Shiraz

Postal code
71345-1978

Approval date
2009-09-27, 1388/07/05

Ethics committee reference number
88-4746

Health conditions studied

1

Description of health condition studied
End stage renal disease , hemodialysis

ICD-10 code
N18

ICD-10 code description

Chronic renal failure

Primary outcomes

1

Description
adiponectin

Timepoint
2 times with 3 months interval

Method of measurement
ELISA kit

2

Description
CRP

Timepoint
2 times with 3 months interval

Method of measurement
ELISA kit

3

Description
homocystein

Timepoint
2 times with 3 months interval

Method of measurement
ELISA kit

Secondary outcomes

1

Description
ferritin

Timepoint
2 times with 3 months interval

Method of measurement
ELISA kit

2

Description
albumin

Timepoint
2 times with 3 months interval

Method of measurement
autoanalyzer

3

Description
transferrin

Timepoint
2 times with 3 months interval

Method of measurement
manual method

4

Description

subjective global assesment

Timepoint

2 times with 3 months interval

Method of measurement

questionnaire

5

Description

food intake

Timepoint

2 times with 3 months interval

Method of measurement

questionnaire

6

Description

quality of life

Timepoint

2 times with 3 months interval

Method of measurement

questionnaire

Intervention groups

1

Description

treatment group: 200 microgram of selenium
supplement per day for 3 months

Category

Treatment - Drugs

2

Description

control group: an starch capsule per day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Faghihi and Nemazi hospitals of Shiraz

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

Zand street

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

Shiraz University of Medical Sciences

Full name of responsible person

Maryam Ekramzade

Position

Master of sciences in nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Position

Associate professor in nutrition

Other areas of specialty/work

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Sharing plan

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Maryam Ekramzade
Position
Master of sciences
Other areas of specialty/work
Street address
Shiraz University of Medical Sciences
City
Shiraz

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