

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

The study of effects serum selenium on serum biomarkers in hemodialysis patients

Protocol summary

Summary

In this study, it has attempted through a study of hemodialysis patients referred to Imam Reza Hospital dialysis ward to determinate serum levels of selenium and its effects on biochemical parameters of patients to decrease the morbidity and mortality of cardiovascular diseases. . This is a double-blind clinical trial which is performed on 100 hemodialysis patients referred to Imam Reza Hospital in Kermanshah. Inclusion criteria: the patient's willingness to cooperate; at least 6 months passing after dialysis starting . Exclusion criteria:hepatitis; other infectious diseases, steroidal and non-steroidal anti-inflammatory drugs or vitamins E,C usage within two months before the study. A written agreement is obtained from hemodialysis patients to participate in this research. 3 cc fasting venous blood is taken from patients before dialysis machine is connected and after hemodialysis finishing, each patient is weighed with a light clothing using a scale with a gram accuracy and also their height is measured with a meter installed on the wall with centimeter accuracy without shoes .General characteristics of the patients are recorded on the data collection sheet. In this study, hemodialysis patients were randomly assigned to receiving selenium supplements group and placebo group. Patients in the receiving group were given selenium supplements for 3 months in form of capsule, while the placebo group received placebo capsules containing starch . On two occasions, before and 90 days after starting of study, blood samples were taken and patients are weighed at the end of the Hemodialysis session.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013081414333N2**

Registration date: **2013-09-17, 1392/06/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-09-17, 1392/06/26

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

fforoughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of effects serum selenium on serum biomarkers in hemodialysis patients

Public title

Serum selenium and its therapeutic effects on serum biomarkers in hemodialysis patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the patient's willingness to cooperate; at least 6 months passing after dialysis starting .

Exclusion criteria: hepatitis; other infectious diseases; steroidal and non-steroidal anti-inflammatory drugs or vitamins E,C usage within two months before the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University Of Medical Sciences

City

Kermnshah

Postal code

Approval date

2013-04-10, 1392/01/21

Ethics committee reference number

646/420/7/پ

Health conditions studied

1

Description of health condition studied

hemodialysis patients

ICD-10 code

N18.0

ICD-10 code description

End-stage renal disease

Primary outcomes

1

Description

selenium

Timepoint

day 0,90

Method of measurement

by cell counter

2

Description

cholesterol

Timepoint

day 0 ,90

Method of measurement

by cell counter

3

Description

H.d.L.

Timepoint

day 0,90

Method of measurement

by cell counter

4

Description

L.D.L

Timepoint

day 0,90

Method of measurement

by cell counter

5

Description

serum

Timepoint

day 0,90

Method of measurement

by cell counter

6

Description

triglycerides

Timepoint

day 0,90

Method of measurement

by cell counter

Secondary outcomes

empty

Intervention groups

1

Description

daily prescription of selenium supplement for 3 months

Category

Treatment - Drugs

2

Description

daily prescription of placebo capsule containing starch for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah Emam Reza Hospital

Full name of responsible person

Dr.Kambiz Jasemi

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Affairs, Kermanshah University Of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University Of Medical Sciences

City

Kermanshah

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Affairs, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Hamid Reza Omrani

Position

Nephrologist

Other areas of specialty/work

Street address

Emam Reza Hospital , Dialysis Ward

City

Kermanshah

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Phone

+98 83 1427 6309

Fax

Email

hamidomrani@yahoo.com

Web page address

Person responsible for updating data

Contact

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