

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### The study of effect of selenium on acute phase reactants and thyroid function test in hemodialysis patients

#### Protocol summary

##### Summary

Objectives: the aim of this study is understanding the effect of selenium on acute phase reactants and thyroid function test in hemodialysis patients. Design: randomised clinical trial. Setting and conduct: after determining the serum level of selenium in hemodialysis patients who referred to Emam Reza hospital, 100 patients who have selenium deficiency divided into 2 groups by age, sex and body mass index. One group treated by selenium capsule 200mg daily for 3 months and the other group treated by placebo capsule. Before and after intervention we measured ESR, CRP, FERRITIN, TSH, T4 and T3RU. Participants including major eligibility criteria: Inclusion criteria: the patient's willingness to cooperate; at least 6 months passing after dialysis starting . Exclusion criteria: infectious diseases during last 3 months; steroidal and non-steroidal anti-inflammatory drugs; vitamins E,C and zinc usage within two months before the study. Interventions: selenium capsule 200 mg daily for 3 months. Placebo capsule daily for 3 months. Main outcome measure: ESR, CRP, FERRITIN, TSH, T4, T3RU

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014041517284N1**

Registration date: **2014-05-20, 1393/02/30**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-05-20, 1393/02/30

##### Registrant information

##### Name

Kanan Nikseresht

##### Name of organization / entity

Kermanshah University of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1427 6300

##### Email address

kanan-nik@kums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah University Of Medical Sciences

##### Expected recruitment start date

2013-03-20, 1391/12/30

##### Expected recruitment end date

2014-03-20, 1392/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The study of effect of selenium on acute phase reactants and thyroid function test in hemodialysis patients

##### Public title

The study of effect of selenium on acute phase reactants and thyroid function test in hemodialysis patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: the patient's willingness to cooperate; at least 6 months passing after dialysis starting . Exclusion criteria: infectious diseases during last 3 months; steroidal and non-steroidal anti-inflammatory drugs; vitamins E, C and zinc usage within two months

before the study.

**Age**

No age limit

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

Not registered

**Secondary trial Id**

Not registered yet

**Registration date**

empty

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

Ethics committee of Kermanshah University of  
Medical Sciences

**Street address**

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

**City**

Kermanshah

**Postal code****Approval date**

2013-09-23, 1392/07/01

**Ethics committee reference number**

۴۹۴۰۱ شماره نامه/۷/۴۲۰/پ

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

Hemodialysis patient

**ICD-10 code**

N18.0

**ICD-10 code description**

End-Stage renal disease

**Primary outcomes****1****Description**

Selenium

**Timepoint**

90 days

**Method of measurement**

By cell counter

**Secondary outcomes****1****Description**

Quantity CRP

**Timepoint**

3 months later

**Method of measurement**

Cell counter

**2****Description**

T3RU

**Timepoint**

3months later

**Method of measurement**

Cell counter

**3****Description**

T4

**Timepoint**

3months later

**Method of measurement**

Cell counter

**4****Description**

TSH

**Timepoint**

3months later

**Method of measurement**

Cell counter

**5****Description**

ESR

**Timepoint**

3months later

**Method of measurement**

Cell counter

**6**

**Description**

Ferritin

**Timepoint**

3months later

**Method of measurement**

Cell counter

**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**

Emam Reza hospital, Kermanshah

**Full name of responsible person**

Dr. Kanan Nikseresht

**Street address**

Internal ward, Emam Reza hospital, Zakaria razi Blvd.

**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

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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**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Kanan Nikseresht

**Position**

Internal medicine resident

**Other areas of specialty/work**

**Street address**

Internal Ward, Emam Reza Hospital, Zakaria razi Blvd.

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**Person responsible for scientific inquiries**

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**Full name of responsible person**

Dr. Hamidreza Omrani

**Position**

Nephrologist

**Other areas of specialty/work**

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**Full name of responsible person**

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**Position**

Internal medicine resident

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**Web page address****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*