Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 determinding the serum level of selenium in hemodialysis patients who refferd to Emam Reza hospital, 100 patients who have selenium defficiency devided 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, FERRRITIN, 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)

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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
٤٩٤٠١ شماره نامه/٧/٤٢٠/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 pacebo 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
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City
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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
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Internal medicine resident
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Person responsible for updating data

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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