

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Investigation of the effect of selenium on thyroid function test in hemodialysis patients

Protocol summary

Study aim

1. Comparison of serum selenium levels before and after treatment with selenium in hemodialysis patients.
- 2- Comparison of serum selenium levels before and after treatment with selenium in hemodialysis patients.

Design

Clinical trial with control group, with parallel, two-way blind, randomized, phase 3 pharmacological study on 66 hemodialysis patients, enrolled between May 2020 to August 2020 . Includes 33 patients in the case group and 33 patients in the control group who were randomly assigned to these two groups. Randomization is done by a table of random numbers.

Settings and conduct

This clinical trial will be performed in hemodialysis centers of Ali Ibn Abitaleb Hospital in Zahedan . Patients will be screened for entry and exit conditions. Patients who volunteer will be included in the study. The serum sample will be taken before receiving the drug and then stored in the refrigerator at -70 degrees. Patients, nurses, drug dealers, and data analysts are blind to the case group. The researcher will personally place patients in the control group or control group through a table of random numbers. The contents of the medicine will be coded by the researcher and others will be unaware of the type of medicine. Patients will receive medication for 12 weeks. After 12 weeks, the final blood sample will be taken.

Participants/Inclusion and exclusion criteria

Participants: All hemodialysis patients Inclusion criteria: The duration of hemodialysis is more than 6 months. Exclusion criteria: Dissatisfaction of the patient, concomitant use of antioxidants at the time of entry into the study, suffering from cancer, any infection during the study, thyroid disease requiring treatment.

Intervention groups

Case group: Treatment with selenium group for 3 months. Control group: Treatment with placebo for 3 months.

Main outcome variables

changes: free T3, freeT4, TSH, rT3, Selenium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047270N1**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Zahra Adineh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3328 5279

Email address

drzahraadineh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-08-21, 1399/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of selenium on thyroid function test in hemodialysis patients

Public title

Evaluation of selenium effect on thyroid function

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Hemodialysis duration more than 6 months

Exclusion criteria:

Sensitivity to selenium Selenium consumption over the past 3 months Thyroid disease needs treatment

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization All eligible hemodialysis patients, if desired, entered the study through a table of random numbers and were placed in two groups of case and control.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher personally puts the drug or placebo in the package and set the patients in the case or control group according to the table of random numbers and numbers the package related to each patient and the others are blind to the type of packaged content. Other people, such as the clinical caregiver and drug distributor and data analyzer, know the groups only on the A and B levels and are blind to the case or control of the groups.

Placebo

Used

Assignment

Parallel

Other design features

Investigation of the effect of selenium on thyroid function in hemodialysis patients

Secondary Ids

empty

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

Ethics Committee of Zahedan University of Medical Sciences

Street address

Ali Ibn Abotaleb ,Khalije fars Boulv.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817958569

Approval date

2019-12-14, 1398/09/23

Ethics committee reference number

IR.ZAUMS.REC.1398.249

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

End Stage Renal Disease

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

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

Changes in serum free T4

Timepoint

At the beginning of the intervention and 12 weeks after the start of the intervention

Method of measurement

Chemi Luminescence

2**Description**

Changes in serum free T4

Timepoint

At the beginning of the intervention and 12 weeks after the start of the intervention

Method of measurement

Chemi Luminescence

3**Description**

Changes in TSH level

Timepoint

At the beginning of the intervention and 12 weeks after the start of the intervention

Method of measurement

Chemi Luminescence

4

Description

Changes in rT3 level

Timepoint

At the beginning of the intervention and 12 weeks after the start of the intervention

Method of measurement

Chemi Luminescence

5

Description

Changes in Selenium level

Timepoint

At the beginning of the intervention and 12 weeks after the start of the intervention

Method of measurement

atomic absorption spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Selenium 200 mg receiving group as oral capsule from 20th Century Pharmaceutical Company for 3 months daily capsule version

Category

Treatment - Drugs

2

Description

Control group: The control group receives the placebo as an oral capsule of exactly the same shape and color of the main drug made by the pharmacy of the research center of the relevant university containing starch for 3 months daily.main drug

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abitaleb hospital

Full name of responsible person

Zahra Adineh

Street address

Khalige fars Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sharaki

Street address

Dctor Heasabi Square

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Zahedan

Province

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981079508569

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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

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Zahra Adineh

Position

Resident assistant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zahedan University of Medical Sciences
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Zahra Adineh
Position
Resident
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data on the main implications of the study will be made available to scientific and service organizations and institutions in a report six months after the end of the intervention.

When the data will become available and for how long

six months after the end of the intervention

To whom data/document is available

All applicants

Under which criteria data/document could be used

The data are available for scientific and academic reasoning and for researchers to investigate similar interventions. The only condition for access is the confidentiality of patient information.

From where data/document is obtainable

Dr. Zahra Adineh By email drzahraadineh@gmail.com

What processes are involved for a request to access data/document

Request via email and state the reason for the request.

Comments