# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

11 Nov 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 3months.

**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.
**City**
Zahedan
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Sistan-va-Balouchestan
**Postal code**
9817958569
**Phone**
+98 54 3328 5279
**Email**
drzahraadineh@gmail.com

## 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
**City**
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**Province**
Sistan-va-Balouchestan
**Postal code**
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**Email**
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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 assisstant
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Internal Medicine
**Street address**
Ali Ibn Abitaleb hospital, Khalige fars Blvd

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## Person responsible for scientific inquiries

**Contact**
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**Full name of responsible person**
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**Position**
Resident
**Latest degree**
Medical doctor
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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**