

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Effect of selenium on lipid profile, Weight gain and Physical Activity in hemodialysis patients

#### Protocol summary

##### Study aim

Determining the mean weight change, changing the lipid profile and changing the physical activity in hemodialysis patients before and after receiving selenium, as well as before and after placebo in the control group

##### Design

This is a double-blind clinical trial and 90 patients with selenium-deficient hemodialysis are non randomly divided into case and control groups.

##### Settings and conduct

This study will be done performed on hemodialysis patients referring to dialysis centers affiliated to Isfahan University of Medical Sciences. At the beginning of the project, 3 cc of venous blood will be taken from all patients, and then Serum levels of selenium will checked. After hemodialysis, the weight of each patient will be measured, the level of lipid profiles and the level of activity of individuals (by five times sit to stand test) will be calculated and recorded. Participants will be treated with medication and placebo for 3 months and after that serum levels of selenium, weight gain, lipid profile and physical activity of individuals will be recalculated and recorded again.

##### Participants/Inclusion and exclusion criteria

The criteria for entering the study are the serum levels of selenium lower than normal, the patient's willingness to co-operate and pass at least 6 months after the onset of hemodialysis; Exit criteria include hepatitis, normal serum levels of selenium, skeletal disorders, and the use of steroid and non-steroidal anti-inflammatory drugs within two months before the start of the study.

##### Intervention groups

Individuals in two groups of 1 and 2 are non randomly divided and a group treated with 2 pills of selenium (200 µg) after each dialysis (3 times a week) and the other group treated with two pill of the placebo after each dialysis dose (3 times a week).

##### Main outcome variables

Lipid profile; Individual weighting; Physical activity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190622043973N1**

Registration date: **2019-08-09, 1398/05/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-08-09, 1398/05/18**

Update count: **0**

##### Registration date

2019-08-09, 1398/05/18

##### Registrant information

##### Name

Hamed Mohamadian Shoeili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3626 3056

##### Email address

hamed429@resident.mui.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-07-06, 1398/04/15

##### Expected recruitment end date

2019-10-07, 1398/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                 |                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Effect of selenium on lipid profile, Weight gain and Physical Activity in hemodialysis patients |                                                                                                                                                                                                                      |
| <b>Public title</b>                                                                             | Effect of selenium on lipid profile, Weight gain and Physical Activity in hemodialysis patients                                                                                                                      |
| <b>Purpose</b>                                                                                  | Treatment                                                                                                                                                                                                            |
| <b>Inclusion/Exclusion criteria</b>                                                             |                                                                                                                                                                                                                      |
| <b>Inclusion criteria:</b>                                                                      | At least 6 months passing after hemodialysis starting The patient's willingness to cooperate                                                                                                                         |
| <b>Exclusion criteria:</b>                                                                      | Hepatitis Skeletal disorder Steroidal and non-steroidal anti-inflammatory drugs within two months before the study                                                                                                   |
| <b>Age</b>                                                                                      | No age limit                                                                                                                                                                                                         |
| <b>Gender</b>                                                                                   | Both                                                                                                                                                                                                                 |
| <b>Phase</b>                                                                                    | N/A                                                                                                                                                                                                                  |
| <b>Groups that have been masked</b>                                                             | <ul style="list-style-type: none"> <li>• Participant</li> <li>• Investigator</li> </ul>                                                                                                                              |
| <b>Sample size</b>                                                                              | Target sample size: <b>90</b>                                                                                                                                                                                        |
| <b>Randomization (investigator's opinion)</b>                                                   | Not randomized                                                                                                                                                                                                       |
| <b>Randomization description</b>                                                                |                                                                                                                                                                                                                      |
| <b>Blinding (investigator's opinion)</b>                                                        | Double blinded                                                                                                                                                                                                       |
| <b>Blinding description</b>                                                                     | In this study, the participants are divided into two groups: 1 and 2, One group of medicines and another group receive placebo. Neither the participants nor the investigators know which drug and which placebo are |
| <b>Placebo</b>                                                                                  | Used                                                                                                                                                                                                                 |
| <b>Assignment</b>                                                                               | Parallel                                                                                                                                                                                                             |
| <b>Other design features</b>                                                                    |                                                                                                                                                                                                                      |
| <b>Secondary Ids</b>                                                                            | empty                                                                                                                                                                                                                |
| <b>Ethics committees</b>                                                                        |                                                                                                                                                                                                                      |
| <b><u>1</u></b>                                                                                 |                                                                                                                                                                                                                      |
| <b>Ethics committee</b>                                                                         |                                                                                                                                                                                                                      |
| <b>Name of ethics committee</b>                                                                 | Ethics committee of Isfahan University of Medical Sciences                                                                                                                                                           |
| <b>Street address</b>                                                                           | Hazar Jarib Street, Azadi Square                                                                                                                                                                                     |
| <b>City</b>                                                                                     | Isfahan                                                                                                                                                                                                              |
| <b>Province</b>                                                                                 | Isfahan                                                                                                                                                                                                              |

|                                                |                                                                     |
|------------------------------------------------|---------------------------------------------------------------------|
| <b>Postal code</b>                             | 8174673461                                                          |
| <b>Approval date</b>                           | 2019-04-11, 1398/01/22                                              |
| <b>Ethics committee reference number</b>       | IR.MUI.MED.REC.1398.006                                             |
| <b>Health conditions studied</b>               |                                                                     |
| <b><u>1</u></b>                                |                                                                     |
| <b>Description of health condition studied</b> | End stage renal disease                                             |
| <b>ICD-10 code</b>                             | N18.5                                                               |
| <b>ICD-10 code description</b>                 | Chronic kidney disease, stage 5                                     |
| <b>Primary outcomes</b>                        |                                                                     |
| <b><u>1</u></b>                                |                                                                     |
| <b>Description</b>                             | Serum triglyceride levels                                           |
| <b>Timepoint</b>                               | Before starting the study and 3 months after the intervention began |
| <b>Method of measurement</b>                   | Autoanalyser                                                        |
| <b><u>2</u></b>                                |                                                                     |
| <b>Description</b>                             | Total serum cholesterol level                                       |
| <b>Timepoint</b>                               | Before starting the study and 3 months after the intervention began |
| <b>Method of measurement</b>                   | Autoanalyser                                                        |
| <b><u>3</u></b>                                |                                                                     |
| <b>Description</b>                             | Weighing                                                            |
| <b>Timepoint</b>                               | Before starting the study and 3 months after the intervention began |
| <b>Method of measurement</b>                   | Scale                                                               |
| <b><u>4</u></b>                                |                                                                     |
| <b>Description</b>                             | Physical activity                                                   |
| <b>Timepoint</b>                               | Before starting the study and 3 months after the intervention began |
| <b>Method of measurement</b>                   | Five times sit to stand test                                        |

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 2 selenium pills (200 micrograms) from Webber Naturals Canada after each hemodialysis (3 times a week) for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Control group: 2 Placebo (Starch) tablets after each hemodialysis (three times a week) for 3 months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hemodialysis Unit of Al-Zahra Hospital

##### Full name of responsible person

Hamed Mohamadian Shoeili

##### Street address

Sofeh Blvd

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3668 5555

##### Fax

+98 31 3668 5555

##### Email

hamed\_23msh@yahoo.com

##### Web page address

<http://alzahra.mui.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Hemodialysis Unit of the Khorshid Hospital

##### Full name of responsible person

Hamed Mohamadian Shoeili

##### Street address

Ostandari Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8145831451

##### Phone

+98 31 3222 2127

##### Email

hamed\_23msh@yahoo.com

##### Web page address

<http://nour.mui.ac.ir/>

### 3

#### Recruitment center

##### Name of recruitment center

Hemodialysis Unit of Amin Hospital

##### Full name of responsible person

Hamed Mohamadian Shoeili

##### Street address

Ibn Sina Street

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8148653141

##### Phone

+98 31 3303 3400

##### Email

hamed\_23msh@yahoo.com

##### Web page address

<https://amin.mui.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Shaghayegh Haghjuy Javanmard

##### Street address

Hazar Jarib Street, Azadi Square

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8138

##### Email

research@mui.ac.ir

##### Web page address

<https://research.mui.ac.ir/>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamed Mohamadian Shoeili

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Nephrology

**Street address**

Isfahan Medical Faculty, Hezarjarib St, Azadi Sq

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Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 8597

**Email**

hamed429@resident.mui.ac.ir

**Web page address**<http://med.mui.ac.ir/>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Abdolamir Atapour

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Nephrology

**Street address**

Khorshid Hospital, Ostandary Street

**City**

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**Province**

Isfahan

**Postal code**

8145831451

**Phone**

+98 31 3222 2127

**Email**

atapour@med.mui.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamed Mohamadian Shoeili

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Isfahan Medical Faculty, Hezarjarib St, Azadi Sq

**City**

Isfahan

**Province**

Isfahan

**Postal code**

7346181746

**Phone**

+98 31 3668 8597

**Email**

hamed429@resident.mui.ac.ir

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

The results of the clinical study Will be published as a paper.

**When the data will become available and for how long**

After giving out the results

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

Scientific use with reference to article

**From where data/document is obtainable**

hamed429@resident.mui.ac.ir

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

Up to one week after correspondence by email  
**Comments**