

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Evaluating the Effect of Zinc supplement on CRP and NLR inflammatory factor in MHD patients

#### Protocol summary

##### Study aim

The effect of zinc supplementation on inflammatory factor CRP and NLR in patients with renal failure undergoing hemodialysis Measurement of serum zinc levels in hemodialysis patients Measurement of serum CRP levels in hemodialysis patients Measurement of NLR in hemodialysis patients using KDQOL-SF1.3 (Kidney Disease Quality of Life Short Form) questionnaire

##### Design

The study is a double-blind prospective randomized clinical trial in crossover form. The number of 40 patients (48 patients including 20% dropout) are randomly divided into two groups of 24 cases.

##### Settings and conduct

Before the start of the first dose of the drug, blood samples are taken from the patients, and the level of serum zinc and the quality of life are recorded by KDQOL-SF 1.3 questionnaire and other investigated factors. After 30 days and at the end of the study (60 days), all aspects will be measured and compared.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-People over 18 years old 2-Zinc level less than 70 mcg / dL 3-Has been on regular hemodialysis for at least six months 4-Undergo hemodialysis at least twice a week. Exclusion criteria: 1- Patient dissatisfaction 2-The patient hospitalized for the last three months 3-Use of zinc supplement during the previous two weeks (use of specific multivitamins for dialysis patients is not concluded) 4-Use of selenium supplement in the last two weeks

##### Intervention groups

After obtaining informed consent from the patients, the first group will be given 50 mg of zinc (one tablet) daily for 30 days, and the second group will receive a placebo tablet. After 30 days, the first group will be given the placebo, and the second group will be assigned 50mg of zinc (one tablet) daily for 30 days.

##### Main outcome variables

CRP,NLR(neutrophil lymphocyte ratio)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160412027346N8**

Registration date: **2022-08-02, 1401/05/11**

Registration timing: **prospective**

Last update: **2022-08-02, 1401/05/11**

Update count: **0**

##### Registration date

2022-08-02, 1401/05/11

##### Registrant information

##### Name

Shadi Ziaie

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8887 3704

##### Email address

shadiziaie@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-08-27, 1401/06/05

##### Expected recruitment end date

2022-10-27, 1401/08/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluating the Effect of Zinc supplement on CRP and NLR inflammatory factor in MHD patients

## Public title

Evaluating the Effect of Zinc supplement on CRP and NLR inflammatory factor in MHD patients

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

People over 18 years old  
Zinc level less than 70 mcg/ dL  
Has been on regular hemodialysis for at least 6 month  
Undergo hemodialysis at least twice a week

### Exclusion criteria:

Patient dissatisfaction  
Have been hospitalized for the last 3 months  
Use of zinc supplement in the last two weeks  
(use of specific multivitamins for dialysis patients is not recommended)  
Use of selenium supplement in the last two weeks

## Age

From **18 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **40**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The drug and placebo were precisely identical in shape and appearance and prepared in similar packaging. A specific code was assigned to the placebo and a code to the drug. Furthermore, it is presented to the patients according to the randomization table. Only the principal investigator will know the code of the drugs. Medicines are given to patients by ward nurses who do not know the code of medicines.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The drug and the placebo are in a package with a standard label and the same amount, and each box is assigned a code that is only available to the researcher, depending on whether it is a drug or a placebo.

## Placebo

Used

## Assignment

Crossover

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Tehran Province, Tehran, Velenjak, Arabi Ave

##### City

Tehran

##### Province

Tehran

##### Postal code

19839-63113

#### Approval date

2022-03-09, 1400/12/18

#### Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.004

## Health conditions studied

### 1

#### Description of health condition studied

End stage kidney disease under hemodialysis

#### ICD-10 code

N18.6

#### ICD-10 code description

End stage renal disease

## Primary outcomes

### 1

#### Description

The effect of zinc supplementation on CRP

#### Timepoint

The beginning of the study, 30 and 60 days

#### Method of measurement

Laboratory test

## Secondary outcomes

### 1

#### Description

The effect of zinc supplementation on NLR (neutrophil,lymphocyte ratio)

#### Timepoint

The beginning of the study, day 30 and 60

#### Method of measurement

laboratory test

## Intervention groups

### 1

#### Description

Intervention group: Administration of 50 mg zinc sulfate

tablets - once a day - orally - for one month -  
manufactured by Alhawi company

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Administration of placebo - once a day - orally

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shahid Labbafinejad Medical center

**Full name of responsible person**

Dr Shadi Ziaie

**Street address**

9th Boostan Pasdaran St Tehran

**City**

Tehran

**Province**

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**Postal code**

5546859685

**Phone**

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Shadiziaie@sbm.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Nima Naderi

**Street address**

Niayesh Highway, Valiasr Ave, Tehran

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**Email**

school.pharmacy@sbmu.ac.ir

**Web page address**

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Shayan Mastoor Tehrani

**Position**

Clinical pharmacy resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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school of pharmacy, Niayesh crossroad, Vali-asr st.

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Shadi Ziaie

**Position**

associate professor

**Latest degree**

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Shayan Mastoor Tehrani  
**Position**  
Clinical pharmacy resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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**Phone**  
+98 21 8820 0118  
**Email**  
Sh.M.Tehrani@sbm.ac.ir

## 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

At the end of the study of all patient data, after making them non-identifiable and performing the statistical analysis mentioned in the work method, necessary reports will be extracted and a part of it related to the main outcome will be shared.

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

6 months after publishing the results

#### To whom data/document is available

responsible investigator, Physicians, academician investigators

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

only with permission of responsible investigator or regulatory bodies

#### From where data/document is obtainable

Responsible investigator

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

Through contacting with responsible investigator

#### Comments