

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effect of oral zinc on nutritional and inflammatory factors in chronic hemodialysis patients

#### Protocol summary

##### Study aim

Evaluation of The effect of oral zinc on nutritional and inflammatory factors in chronic hemodialysis patients in Boali hospital

##### Design

randomized clinical trial with control group.single blind

##### Settings and conduct

The trial was conducted at Boo Ali Hospital in Tehran and randomly divided into two groups of intervention and control.

##### Participants/Inclusion and exclusion criteria

inclusion criteria:hemodialysis patients consent to participate in study Exclusion criteria:Patients receiving tetracycline and quinolone.

##### Intervention groups

The intervention group consisted of patients who received two capsules of 110 mg zinc sulfate daily along with their other medications for 3 months. The control group consisted of patients who received 2 capsules of 110 mg zinc sulfate daily along with their other medications for 3 months.

##### Main outcome variables

Hba1c,predialysis  
BUN,albumin,hemoglobin,TG,ESR,ferritin,crp

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150706023084N5**  
Registration date: **2020-04-06, 1399/01/18**  
Registration timing: **retrospective**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

##### Registration date

2020-04-06, 1399/01/18

#### Registrant information

##### Name

MARYAM SHIEHMORTEZA

##### Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

##### Country

Iran (Islamic Republic of)

##### Phone

+98 212640056

##### Email address

shiehmorteza@iaups.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2019-05-21, 1398/02/31

##### Expected recruitment end date

2019-08-22, 1398/05/31

##### Actual recruitment start date

2019-05-21, 1398/02/31

##### Actual recruitment end date

2019-08-22, 1398/05/31

##### Trial completion date

2019-08-22, 1398/05/31

#### Scientific title

The effect of oral zinc on nutritional and inflammatory factors in chronic hemodialysis patients

#### Public title

Evaluation of the effect of oral zinc in patients with chronic hemodialysis

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Hemodialysis patients consenting to participate in the study

##### Exclusion criteria:

Patients receiving tetracycline and quinolone.

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patient serum sample

Actual sample size reached: **80**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Patient serum sample

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization Method: Simple randomization

Randomization tool: Random Number Table

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

All patients who were included in the study were randomly assigned to either drug or placebo groups by random number table. Patients were unaware of the drug or placebo intervention. But the researcher and the doctor were aware of the drug or placebo. Patients and medications were coded by the researcher. The blinding was such that the placebo was the same color and flavor as the drug. That is, the drug and the placebo were both similar in appearance. But the placebo capsules contained cornstarch.

**Placebo**

Used

**Assignment**

Single

**Other design features****Secondary Ids**

empty

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

Ethics committee of Department of Pharmaceutical Sciences, Tehran Islamic Azad University of Medical

**Street address**

Dr Shariati Ave., Gholhak, Yakhchal Ave., Islamic Azad University of Pharmaceutical Sciences Branch

**City**

Tehran

**Province**

Tehran

**Postal code**

193956466

**Approval date**

2019-01-05, 1397/10/15

**Ethics committee reference number**

IR.IAU.PS.REC.1397.324

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

Inflammation and malnutrition in patients with chronic hemodialysis

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

HBA1C

**Timepoint**

Before the start of the study and three months after taking oral zinc tablets

**Method of measurement**

Variable serum levels were measured by chromatography

**2****Description**

Albumin

**Timepoint**

Before the start of the study and three months after taking oral zinc tablets

**Method of measurement**

The serum levels of the variable were measured by Bromocresol Green.

**3****Description**

BUN or blood urea nitrogen

**Timepoint**

Before the start of the study and three months after taking oral zinc tablets

**Method of measurement**

Serum levels of variable blood were measured by tacophoresis.

**4****Description**

Hemoglobin

**Timepoint**

Before the start of the study and three months after taking oral zinc tablets

**Method of measurement**

Serum levels of variable blood were measured by cyanometho hemoglobin.

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### **Description**

Triglycerides

### **Timepoint**

Before the start of the study and three months after taking oral zinc tablets

### **Method of measurement**

The serum levels of the variable blood were measured by a special kit using triglyceride oxidase.

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### **Description**

ESR or erythrocyte sedimentation rate

### **Timepoint**

Before the start of the study and three months after taking oral zinc

### **Method of measurement**

The serum level of the variable in question was measured by the Westergreen method.

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### **Description**

ferritin

### **Timepoint**

Before the start of the study and three months after taking oral zinc

### **Method of measurement**

Serum levels of variable blood were measured by RIA.

## 8

### **Description**

CRP or C reactive protein

### **Timepoint**

Before the start of the study and three months after taking oral zinc

### **Method of measurement**

Blood serum levels of the variable were measured with special latex agglutination kits.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The group received 2 capsules of zinc sulfate 110 mg daily along with their other medications.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: The group received 2 placebo capsules of zinc sulfate 110 mg daily along with their other medications.

## **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Booali Hospital, Tehran

##### **Full name of responsible person**

Dr.farahnaz pasha

##### **Street address**

Tehran - Imam Hossein Square - At the beginning of Damavand Street

##### **City**

tehran

##### **Province**

Tehran

##### **Postal code**

17117

##### **Phone**

+98 21 3334 8036

##### **Fax**

##### **Email**

booali.hospital96@gmail.com

##### **Web page address**

<http://bouali.iautmu.ac.ir/fa>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Islamic Azad University

##### **Full name of responsible person**

Dr.farshad hashemian

##### **Street address**

Tehran. Islamic Azad University of Medical Sciences

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##### **Fax**

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##### **Email**

info@iau.ac.ir

##### **Web page address**

<http://iaups.iautmu.ac.ir/fa>

#### **Grant name**

#### **Grant code / Reference number**

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

No

#### **Title of funding source**

Student herself

#### **Proportion provided by this source**

100  
**Public or private sector**  
Private  
**Domestic or foreign origin**  
Domestic  
**Category of foreign source of funding**  
*empty*  
**Country of origin**  
**Type of organization providing the funding**  
Persons

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Islamic Azad University  
**Full name of responsible person**  
hanieh bahrami tabar  
**Position**  
University student  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Kangavar, Taleghani Street, the end of Keshavarzi  
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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Position**  
University student  
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Medical doctor  
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hanieh.bahramitabar@gmail.com

## 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

Undecided - It is not yet known if there will be 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