

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### The effect of zinc sulfate on serum copeptin, C-Reactive protein, insulin resistance and nutritional status in diabetic hemodialysis patients

#### Protocol summary

##### Study aim

Determination the effect of zinc sulfate on serum copeptin, CRP, insulin resistance and nutritional status in diabetic hemodialysis patients

##### Design

Randomized double-blind placebo controlled clinical trial

##### Settings and conduct

This study is double blind, placebo controlled clinical trial; Patients and nurses and statistics Adviser do not know about the drug and placebo. Diabetic hemodialysis patients form at the Imam Ali Dialysis Center (Zahedan, Iran) will randomly divided into 2 groups (case=20, control=20) to receive 220 mg zinc sulfate (containing 50 mg zinc) supplements or placebo (220-mg corn starch) per day for 8 weeks. Fasting blood samples were taken at baseline and after 8 weeks' intervention to quantify copeptin, CRP and insulin. Also for determining nutritional status the Food Frequency Questionnaire will be completed by expert before and after 8-week intervention.

##### Participants/Inclusion and exclusion criteria

Diabetic hemodialysis patients(Pass at least 6 months from hemodialysis); Age:15-70; Not having inflammatory diseases affecting on serum inflammatory markers; One month before the study began no supplements containing antioxidants, Zinc supplement, vitamins E and C supplements; Steroid and non-steroidal anti-inflammatory drugs should not be used. If the patients have been taking antibiotics for the past month and with infectious or feverish disease. Also diseases affecting on serum copeptin like severe cardiovascular disease, hypothyroidism, hyperthyroidism and sepsis are not included in this study.

##### Intervention groups

Diabetic hemodialysis patients in the zinc-supplementation group will receive a 220mg zinc sulfate capsule(n=20) manufactured by Alhavi Pharmaceutical Company (Tehran, Iran) and the control-group(n=20) will receive a placebo capsule(220mg corn starch), for 56

days.

##### Main outcome variables

Copeptin; Insulin; CRP; Nutritional status

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190806044461N1**

Registration date: **2019-08-23, 1398/06/01**

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

Last update: **2019-08-23, 1398/06/01**

Update count: **0**

##### Registration date

2019-08-23, 1398/06/01

##### Registrant information

##### Name

Razieh Hosseini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 4252 0479

##### Email address

razieh.hosseini7759@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-08-23, 1398/06/01

##### Expected recruitment end date

2019-09-23, 1398/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The effect of zinc sulfate on serum copeptin, C-Reactive protein, insulin resistance and nutritional status in diabetic hemodialysis patients

**Public title**  
Effect of zinc sulfate in diabetic hemodialysis patients

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Diabetic hemodialysis patients(Pass at least 6 months from hemodialysis); Age:15-70; Not having inflammatory diseases affecting on serum inflammatory markers; One month before the study began no supplements containing antioxidants,zinc supplement, vitamins E and C supplements; Steroid and non-steroidal anti-inflammatory drugs should not be used.  
**Exclusion criteria:**  
If the patients have been taking antibiotics for the past month and with infectious or feverish disease. Also Diseases affecting serum copeptin like severe cardiovascular disease, Hypothyroidism ,hyperthyroidism and sepsis are not included in this study.

**Age**  
From **15 years** old to **70 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Diabetic hemodialysis patients with inclusion criteria enter as available. Then they will be divided into two groups(case and control) using the file number through random variable.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients and nurses ward and statistics Adviser do not know about the drug and placebo.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Zahedan University of medical sciences

**Street address**

No. 9, Dr shariati Ave.

**City**

Nour Abad

**Province**

Fars

**Postal code**

73517-38177

**Approval date**

2019-07-21, 1398/04/30

**Ethics committee reference number**

IR.ZAUMS.REC.1398.207

## Health conditions studied

### 1

**Description of health condition studied**

Chronic kidney disease

**ICD-10 code**

N18.5

**ICD-10 code description**

Chronic kidney disease, stage 5

## Primary outcomes

### 1

**Description**

Serum copeptin

**Timepoint**

Before and after 8-week intervention

**Method of measurement**

It measured by ELISA method with standard kit

### 2

**Description**

Serum insulin

**Timepoint**

Before and after 8-week intervention

**Method of measurement**

It measured by ELISA method with standard kit

### 3

**Description**

C-Reactive-Protein

**Timepoint**

Before and after 8-week intervention

**Method of measurement**

It measured by ELISA method with standard kit

## 4

### Description

Nutritional status

### Timepoint

Before and after 8-week intervention

### Method of measurement

Food Frequency Questionnaire

## Secondary outcomes

### 1

#### Description

Insulin resistance

#### Timepoint

Before and after 8-week intervention.

#### Method of measurement

Homeostasis model assessment measuring insulin resistance

## Intervention groups

### 1

#### Description

Intervention group: The zinc-supplementation group(n=20) will receive a 220-mg zinc sulfate capsule(containing 50 mg zinc) manufactured by Alvahi Pharmaceutical Company (Tehran, Iran); for 8 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group:The control-group(n=20) will receive a placebo capsule(220-mg corn starch), for 8 weeks.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Ali Dialysis Center

##### Full name of responsible person

Elham shahreki

##### Street address

Imam Ali Hospital; Salamat Blvd; khaliye Fars High road

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

98167-43111

##### Phone

+98 54 3329 5564

##### Email

shahreki@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zahedan University of Medical Sciences

##### Full name of responsible person

Nour Mohammad Bakhshani

##### Street address

Dr Hesabi Sq; Khalije Fars Blvd; Zahedan; Iran.

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

##### Phone

+98 54 3329 5796

##### Email

nmbakhsha@zdmv.ac.ir

#### 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

Razieh Hosseini

##### Position

Student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nutrition

##### Street address

No 9; Dr Shariati Ave.

##### City

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##### Province

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##### Postal code

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Razieh Hosseini

**Position**

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**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Razieh Hosseini

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

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73517-38177

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**Email**

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**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