

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 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 Alvavi 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; Khaliye 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

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Person responsible for scientific inquiries

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Latest degree

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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