

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of zinc sulfate- hydroxyzine and hydroxyzine alone on malnutrition indices in hemodialysis patients: A clinical trial

Protocol summary

Summary

The aim of this study: Comparison of the effect of zinc sulfate- hydroxyzine and hydroxyzine alone on malnutrition indices in hemodialysis patients. Study design: After explaining the purpose of the study and obtaining the informed consent, patients under hemodialysis will be allocated into A and B groups. Randomization will be performed using random block sizes of 4. The study is single-center, phase 3 trial and patients and physician will be blind about the type of drugs. Inclusion criteria: More than 15 years old; history of at least 6 months hemodialysis. Exclusion criteria: zinc supplements usage; nephrotic syndrome; cancer. Sample size: 84 patients will participate in the study with 42 patients in each group. Study groups: Intervention group: one zinc sulfate capsule (220 mg) daily and one hydroxyzine tablet (25 mg) daily for 8 weeks. Control group: one hydroxyzine tablet (25 mg) daily for 8 weeks. Primary outcomes: BMI, Albumin, Cholesterol, Hemoglobine, Creatinin, Arm durchmesser

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102136703N2**

Registration date: **2017-11-08, 1396/08/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-08, 1396/08/17

Registrant information

Name

Elahe Hoseini

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23233390433

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hossaini@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of zinc sulfate- hydroxyzine and hydroxyzine alone on malnutrition indices in hemodialysis patients: A clinical trial

Public title

Effect of zinc sulfate- hydroxyzine and hydroxyzine alone on malnutrition indices in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: More than 15 years old; history of at least 6 months hemodialysis. Exclusion criteria: Zinc supplements usage; nephrotic syndrome; cancer

Age

From **15 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Vice chancellor for research,
Shahroud University of Medical Sciences

Street address

Shahroud University of Medical Sciences, Hafte-Tir
Square

City

Shahroud

Postal code

3613773955

Approval date

2017-08-25, 1396/06/03

Ethics committee reference number

IR.SHMU.REC.1396.63

Health conditions studied

1

Description of health condition studied

End stage renal disease, hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic renal failure

Primary outcomes

1

Description

BMI

Timepoint

Before the intervention and 4 and 8 weeks after
intervention

Method of measurement

Wt(kg)/Ht(m²)

2

Description

Albumin

Timepoint

Before the intervention and 4 and 8 weeks after
intervention

Method of measurement

Autoanalyzer

3

Description

Cholesterol

Timepoint

Before the intervention and 4 and 8 weeks after
intervention

Method of measurement

Autoanalyzer

4

Description

Hemoglobine

Timepoint

Before the intervention and 4 and 8 weeks after
intervention

Method of measurement

Cell Blood Count with sismex k1000

5

Description

Creatinin

Timepoint

Before the intervention and 4 and 8 weeks after
intervention

Method of measurement

Autoanalyzer

6

Description

Arm Durchmesser

Timepoint

Before the intervention and 4 and 8 weeks after
intervention

Method of measurement

Meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one zinc sulfate capsule (220 mg) daily and one hydroxyzine tablet (25 mg) daily for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: one hydroxyzine tablet (25 mg) daily for 8 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein hospital

Full name of responsible person

Dr Monire Amerian

Street address

Imam Hossein Hospital, End of Ayatollah Towhidi avenue, Shahroud

City

Shahroud

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahroud University of Medical Sciences

Full name of responsible person

Mohammad Hasan Emamian

Street address

Shahroud University of Medical Sciences, 7 Tir square, Shahroud

City

Shahroud

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Azita Roohi

Position

Medical Student

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty