Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of zinc sulfate and placebo on sleep quality in hemodialysis patients: A clinical trial

Protocol summary

Summary

The aim of this study: Comparison of the effect of zinc sulfate and placebo on sleep quality 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, double blind and phase 3 trial and patients and physician will be blind about the type of drugs. Inclusion criteria: History of at least 6 months hemodialysis for three time in week; sleep quality score lower than 5. Exclusion criteria: zinc supplements usage; immunosuppressive drugs usage; history of psychiatric, cardiopolmonary and infectious disease in three past months. Sample size: 100 patients will participate in the study with 50 patients in each group. Study groups: Intervention group: one Zinc sulfate capsule (220 mg) daily for one month and then two zinc sulfate capsule (440 mg) daily for second months. Control group: one placebo capsule daily for one month and then two placebo capsule daily for second months. Primary outcome: Sleep quality

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101036703N1**
Registration date: **2017-11-17, 1396/08/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-11-17, 1396/08/26

Registrant information

Name

Elahe Hoseini

Name of organization / entity

Shahroud University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahroud University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of zinc sulfate and placebo on sleep quality in hemodialysis patients: A clinical trial

Public title

Effect of zinc sulfate on sleep quality in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: History of at least 6 months hemodialysis for three time in week; sleep quality score lower than 5. Exclusion criteria: Zinc supplements usage; immunosuppressive drugs usage; history of psychiatric, cardiopolmonary and infectious disease in three past

months.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization will be performed using random block sizes of 4

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 and Health Services, Hafte-Tir Square

City

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Postal code

3613773955

Approval date

2017-08-12, 1396/05/21

Ethics committee reference number

IR.SHMU.REC.1396.76

Health conditions studied

1

Description of health condition studied

zinc deficiency

ICD-10 code

E60

ICD-10 code description

Dietary zinc deficiency

Primary outcomes

1

Description

Sleep quality

Timepoint

Before the intervention and 8 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Index questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one Zinc sulfate capsule (220 mg) daily for one month and then two zinc sulfate capsule (440 mg) daily for second months.

Category

Treatment - Drugs

2

Description

Control group: one placebo capsule daily for one month and then two placebo capsule daily for second months

Category

Placebo

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

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Shahroud University of Medical Sciences, 7 Tir square, Shahroud

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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

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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