

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 23233390433

Email address

hossaini@shmu.ac.ir

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

Shahroud

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

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
Elahe Hosseini

Position
Medical Student

Other areas of specialty/work

Street address
Shahroud University of Medical Sciences, Hafte-Tir Square, Shahroud

City
Shahroud

Postal code

Phone
+98 23 3239 1796

Fax

Email
hosseini@shmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Dr Monire Amerian

Position

Nephrologist

Other areas of specialty/work

Street address
Imam Hossein Hospital, End of Ayatollah Towhidi avenue

City
Shahroud

Postal code
3613773955

Phone
+98 23 3239 1796

Fax

Email
amerian@shmu.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahroud University of Medical Sciences

Full name of responsible person
Elahe Hosseini

Position
Medical student

Other areas of specialty/work

Street address
Shahroud University of Medical Sciences and Health Services, Hafte-Tir Square, Shahroud

City
Shahroud

Postal code
3613773955

Phone
+98 23 3239 1796

Fax

Email

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