

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of Zinc sulfate on sleep quality in chemotherapy patients in Imam Hossain hospital of Shahroud , a randomized clinical trial

#### Protocol summary

##### Study aim

Determining the effect of zinc sulfate on sleep quality in patients undergoing chemotherapy

##### Design

This is a parallel randomized controlled clinical trial that will be performed on 100 hemodialysis patients with sleep disorders. Randomization in this research is done using quadri blocks using syntax written in SPSS program. The duration of the study will be 2 months.

##### Settings and conduct

This study will conduct as a clinical trial study with 100 patients who will refer to Imam Hossain Hospital of Shahroud. Patients must sign an informed consent form before entering the study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with breast and blood cancer undergoing chemotherapy with low sleep quality (Global Score <5), Chemotherapy for at least the last four months, Perform chemotherapy for at least once every 15 days, Do not take any sleeping drugs for at least the past month and Having informed consent to participate in research. Exclusion criteria: Patients with cancers other than breast and blood, Use supplements containing zinc or fish oil at least one month before the study, Existence of severe heart and respiratory diseases for at least one month, Patients who have had a bone marrow transplant and then returned to chemotherapy, History of severe mental illness for at least the last three months, History of severe mental illness for at least the last three months and Dissatisfaction with participation in research.

##### Intervention groups

Patients included in the study are divided into intervention and control groups. In the intervention group, treatment with zinc sulfate tablets will be prescribed. In the control group, placebo treatment will be prescribed.

##### Main outcome variables

Sleep quality assessment and CRP measurement

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100102002954N20**

Registration date: **2020-09-26, 1399/07/05**

Registration timing: **prospective**

Last update: **2020-09-26, 1399/07/05**

Update count: **0**

##### Registration date

2020-09-26, 1399/07/05

##### Registrant information

##### Name

Mohammad Bagher Sohrabi

##### Name of organization / entity

Shahroud University of Medical Ssciences and Health

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3239 5054

##### Email address

mb.sohrabi@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-21, 1399/07/30

##### Expected recruitment end date

2021-01-18, 1399/10/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Effect of Zinc sulfate on sleep quality in chemotherapy patients in Imam Hossain hospital of Shahroud , a randomized clinical trial

## Public title

The effect of zinc sulfate on sleep quality in patients undergoing chemotherapy

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with breast and blood cancer undergoing chemotherapy with low sleep quality (Global Score <5), Chemotherapy for at least the last four months, Perform chemotherapy for at least once every 15 days, Do not take any sleeping drugs for at least the past month, Having informed consent to participate in research.

### Exclusion criteria:

Patients with cancers other than breast and blood Use supplements containing zinc or fish oil at least one month before the study Existence of severe heart and respiratory diseases for at least one month Patients who have had a bone marrow transplant and then returned to chemotherapy History of severe mental illness for at least the last three months History of severe mental illness for at least the last three months

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: 100

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients were allocated to intervention and control groups according to random allocation table that illustrated by a statistician. Randomization was done using permuted block randomization method (Block size was 4) using blocked random allocation syntax in SPSS software. For calculation sample size was 100 and number of blocks was 25. Allocation concealment was done using closed opaque envelope.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahroud University of Medical Sciences

##### Street address

Shahroud University of Medical Sciences; 7 Tir squer, Shahroud

##### City

Shahroud

##### Province

Semnan

##### Postal code

3616647555

#### Approval date

2019-09-29, 1398/07/07

#### Ethics committee reference number

IR.SHMU.REC.1398.076

## Health conditions studied

### 1

#### Description of health condition studied

End-stage renal disease

#### ICD-10 code

N18.0

#### ICD-10 code description

End-stage renal disease

### 2

#### Description of health condition studied

Nonorganic sleep disorders

#### ICD-10 code

F51

#### ICD-10 code description

Nonorganic sleep disorders

## Primary outcomes

### 1

#### Description

Sleep quality assessment

#### Timepoint

Once a month

#### Method of measurement

Ask the patient and using the standard Petersberg Sleep Quality Assessment Questionnaire

## Secondary outcomes

### 1

#### Description

CRP measurement

#### Timepoint

Once a month

**Method of measurement**

Laboratory method

**Intervention groups****1****Description**

Intervention group: Patients in the intervention group are prescribed one 220 mg zinc sulfate tablet daily for the first month and then two zinc sulfate tablets (440 mg) daily for the second month.

**Category**

Treatment - Drugs

**2****Description**

Control group: Patients in the control group will be given one starch tablet apparently similar to a placebo daily for the first month and then two placebo tablets daily for the second month.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital of Shahroud

**Full name of responsible person**

Dr. Ali Najafi

**Street address**

Imam Hossein Hospital., End Imam street., Shahroud , Iran

**City**

Shahroud

**Province**

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**Postal code**

3616611151

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anajafi@yahoo.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Hasan Emamian

**Street address**

Vice chancellor for research; Shahroud University

medical Sciences ,7th Tir squar, Shahroud

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pajouhesh@shmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Vice chancellor for research; Shahroud University medical and 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**

Shahroud University of Medical Sciences

**Full name of responsible person**

Fateme Hasanifard

**Position**

General Practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

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fatemehasanifard@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Ali Najafi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr.Mohammad Bagher Sohrabi

**Position**

General Practitioner

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available