

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)

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+98 23 3239 5054

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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

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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

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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

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Vice chancellor for research; Shahroud University

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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

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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

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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

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