Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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

Ḍr. Ali Najafi

Street address

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

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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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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

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Name of organization / entity
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Dr. Ali Najafi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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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