Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of zinc supplement on sleep quality in ICU nurses

Protocol summary

Summary

This study is a double-blind randomized clinical trial (RCT). The aim of this study is to evaluate the effect of zinc supplement on sleep quality of ICU nurses. 54 nurses, who qualified for study entry, randomly allocate in two equal groups. Inclusion criteria are: low sleep quality; low serum zinc level; full-time nurses with a bachelor's degree or higher; minimum of one year experience in ICU. Exclusion criteria are: unwillingness to continue the study; history of diabetes, psychiatric, gastrointestinal, autoimmune, rheumatic disease; micronutrients and supplements usage; cigarette Smoking. Intervention group receive one Zinc sulfate 220 mg capsule every 72 hour for one month and control group receive one placebo capsule per 72 hour for one month. Before and at the end of the trial, Pittsburgh Sleep Quality Index questionnaire will be completed by nurses and for measuring of serum Zinc, cooper and CBC, five milliliter blood will be sampled from antecubital vein. After collecting and classifying of information, data will be analyzed with SPSS18

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202104365N11**
Registration date: **2012-04-06, 1391/01/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-06, 1391/01/18

Registrant information

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Afshin Gholipour Baradari
Name of organization / entity
Mazandaran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2012-02-09, 1390/11/20

Expected recruitment end date

2012-03-10, 1390/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplement on sleep quality in ICU nurses

Public title

Effect of zinc supplement on sleep quality in ICU nurses

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: low sleep quality; low serum zinc level; full-time nurses with a bachelor's degree or higher; minimum of one year experience in ICU. Exclusion criteria: unwillingness to continue the study; history of diabetes, psychiatric, gastrointestinal, autoimmune, rheumatic disease; micronutrients and supplements usage; cigarette Smoking.

Age

No age limit

Gender

Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic committee of Mazandaran University of Medical Sciences
Street address
Mazandaran University of Medical Sciences, Moallem Square
City
Sari
Postal code
46175866
Approval date
2012-02-08, 1390/11/19
Ethics committee reference number
90-177

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 intervention and one months later
Method of measurement
Pittsburgh Sleep Quality Index questionnaire

Secondary outcomes

1

Description
Serum Zinc level
Timepoint
before trial,one months later
Method of measurement
Laboratory kit

Intervention groups

1

Description
Intervention group receive one Zinc sulfate 220 mg capsule per 72 hour for one month
Category
Treatment - Drugs

2

Description
control group receive one placebo capsule per 72 hour for one month
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini General Hospital
Full name of responsible person
Afshin Gholipour Baradari, MD
Street address
Imam Khomeini general Hospital, Amir St, Sari, Iran
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2

Recruitment center
Name of recruitment center
Mazandaran heart center
Full name of responsible person
Afshin Gholipour Baradari, MD
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Mazandaran University of Medical Sciences
Full name of responsible person
Ahmad Ali Enayati MD
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Mazandaran university of medical sciences, Moallem Square- Sari- Iran
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Sari
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 of Mazandaran 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
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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