

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Afshin Gholipour Baradari

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3326 1245

Email address

gholipourafshin@mazums.ac.ir

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

City

Sari

2**Recruitment center****Name of recruitment center**

Mazandaran heart center

Full name of responsible person

Afshin Gholipour Baradari, MD

Street address

Mazandaran Heart center, Artesh Blvd, Sari, Iran

City

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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

Street address

Mazandaran university of medical sciences, Moallem Square- Sari- Iran

City

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**Name of organization / entity**

Mazandaran University Of Medical Sciences

Full name of responsible person

Afshin Gholipour Baradari MD

Position

CCMF, Assistant Professor, Chief of ICU

Other areas of specialty/work**Street address**

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Person responsible for scientific

inquiries

Contact**Name of organization / entity**

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Mazandaran University of Medical Sciences

Full name of responsible person

Hadi Darvishi

Position

MSc

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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