

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Zinc Supplementation on Sleep quality and fatigue in the elderly

Protocol summary

Summary

Objective: Determining the effect of Zinc Supplement on Sleep quality and fatigue in the elderly. Design: This study is a clinical trial study in which questioners and data analysts have been blinded. Study population: Seniors 60 years and older in Kashan. Main inclusion criteria: Having full satisfaction to participate in this study; Iranian citizenship; not using Zinc Supplement; no cognitive impairment; lack of liver and intestinal diseases diagnosed by the doctor and People with serum zinc levels in them based on experiment within be normal range. Main exclusion criteria: The lack of cooperation and refusal of the elderly to continue to participate in research; consumption of Zinc Supplement in the control group during the course of 70 days of intervention; The occurrence of severe stress in both groups during the study. Those who did not use sleep medications before the intervention began but after the intervention begins and in the 70-day study period taking a sleep medication will be excluded. For city-level sampling first, the health centers that cover the population groups they are considered as clusters. Then, relative to the number of the elderly located in each cluster 150 elderly they will be selected by stratified sampling. To measure serum zinc level 5 ml venous blood sample taken in fasting conditions of the elderly both intervention and control groups and sent to lab; Then PSQI sleep quality inventory and MFI fatigue inventory will be completed by the elderly. For the elderly of the intervention group for 10 weeks Zinc supplement 30 milligrams which will be given in the form of Zinc Gluconate. In the elderly, Zinc supplementation control group will not be used. After 70 days serum zinc level will be measured again as well as questionnaires will be completed by the elderly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080635110N2**

Registration date: **2017-09-07, 1396/06/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-07, 1396/06/16

Registrant information

Name

Abolfazli Afzali

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 31 5551 2727

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research (Research and Technology),
Shahroud University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Zinc Supplementation on Sleep quality and fatigue in the elderly

Public title

The effect of Zinc Supplementation on Sleep quality and fatigue in the elderly

Purpose

Prevention

Inclusion/Exclusion criteria

"The inclusion criteria for this study are": having full satisfaction to participate in this study; seniors 60 years and older; Iranian citizenship; the ability to speak Farsi and answer questions; not using Zinc Supplement; no cognitive impairment (for the elderly with literacy based on the MMSE questionnaire score 25 and more and for the illiterate elderly, based on the AMTS questionnaire, score 7 and more); lack of liver and intestinal diseases to diagnose a doctor, people with serum zinc levels in them based on experiment within be normal range; in that sense people whose serum zinc level is higher or lower than normal range do not enter the study. Elderly people with low sleep quality; according to Pittsburgh sleep quality questionnaire, gaining a score of over 5 in the entire questionnaire is means poor sleep quality. "The exclusion criteria for this study are": the lack of cooperation and refusal of the elderly to continue to participate in research; the consumption of zinc supplement in the control group during the course of 70 days of intervention; the occurrence of severe stress, such as hospitalization or death of relatives in both groups during the study; those who did not use sleep medications before the intervention began but after the intervention begins and in the 70-day study period taking a sleep medication will be excluded.

Age

From **60 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Select clusters is based on socioeconomic conditions of the people of Kashan city. Random assignment to test and control groups based on randomized software in the form of four blocks will be grouped and in two groups A (intervention) And group B (control) will be placed. Zinc measurements in a laboratory in Kashan and will be done by auto-analysis. Relaxation exercises will be taught if aging after 70 days of low sleep quality or high fatigue is based on Pittsburgh Sleep Quality and MFI Inventory.

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, Hafte-Tir Square

City

Shahroud

Postal code

Approval date

2017-08-13, 1396/05/22

Ethics committee reference number

IR.SHMU.REC.1396.80

Health conditions studied

1

Description of health condition studied

Sleep Quality

ICD-10 code

G47

ICD-10 code description

Sleep disorders

2

Description of health condition studied

Fatigue

ICD-10 code

R53

ICD-10 code description

Malaise and fatigue

Primary outcomes

1

Description

Sleep Quality

Timepoint

Before the intervention and 70 days after the intervention began

Method of measurement

PSQI standard questionnaire

2

Description

Fatigue

Timepoint

Before the intervention and 70 days after the intervention began

Method of measurement
MFI standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group: Zinc supplemented pill is a zinc gluconate form and it contains 30 mg zinc for 70 days will be given to elderly group intervention. One day one of these pills after lunch meal is used together with a glass of water.

Category

Treatment - Drugs

2

Description

In the control group: No action is taken.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ravand Health Center

Full name of responsible person

Abolfazl Afzali

Street address

Haram Stree,: Ravand

City

Kashan

2

Recruitment center

Name of recruitment center

Sadoughi Health Center

Full name of responsible person

Abolfazl Afzali

Street address

Gendarmerie Street

City

Kashan

3

Recruitment center

Name of recruitment center

Imam Ali Health Center

Full name of responsible person

Abolfazl Afzali

Street address

2nd Phase, Naji Abad

City

Kashan

4

Recruitment center

Name of recruitment center

Greater Fin Health Center

Full name of responsible person

Abolfazl Afzali

Street address

Above the bank, Greater Fin

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research - Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad-Hassan Emamian

Street address

Shahroud University of Medical Sciences, Hafte-Tir Square

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Shahroud

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 - Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Abolfazl Afzali

Position

Master of Geriatric Nursing

Other areas of specialty/work

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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*