

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

The effect of Zinc Supplementation on mood, anxiety and quality of life in the elderly of Kashan

Protocol summary

Summary

Objective: Determining the effect of Zinc Supplement on mood, anxiety and quality of life 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 as well as the absence of known cases of depression and anxiety both of these are diagnosed by the doctor. 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. 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 GDS depression inventory, Anxiety BAI and quality of life SF-36 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. 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: **IRCT2017071635110N1**

Registration date: **2017-08-01, 1396/05/10**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-08-01, 1396/05/10

Registrant information

Name

Abolfazl Afzali

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 5551 2727

Email address

afzali.a1373@shmu.ac.ir

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 mood, anxiety and quality of life in the elderly of Kashan

Public title

Investigating the effect of Zinc Supplement on mood, anxiety and quality of life 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 as well as the absence of known cases of depression and anxiety both of these are diagnosed by the 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. 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.

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)

Not 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. In order to comply with ethical principles elderly both groups which after 70 days of intervention their zinc level is below normal To the expert physician will be referred.

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

2017-06-20, 1396/03/30

Ethics committee reference number

IR.SHMU.REC.1396.42

Health conditions studied

1

Description of health condition studied

Mood (depression)

ICD-10 code

F30-F39

ICD-10 code description

Mood [affective] disorders

2

Description of health condition studied

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

3

Description of health condition studied

Quality of life

ICD-10 code

Y98

ICD-10 code description

Lifestyle-related condition

Primary outcomes

1

Description

Mood(depression)

Timepoint

Before the intervention and 70 days after the intervention began

Method of measurement

GDS standard questionnaire

2

Description

Anxiety

Timepoint

Before the intervention and 70 days after the intervention began

Method of measurement

BAI standard questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

Before the intervention and 70 days after the intervention began

Method of measurement

SF-36 standard questionnaire

Intervention groups

1

Description

In the control group: No action is taken.

Category

N/A

2

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

Recruitment centers

1

Recruitment center

Name of recruitment center

Ravand health center

Full name of responsible person

Abolfazl Afzali

Street address

Ravand _ Haram Street

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

Naji Abad _ Two Phases

City

Kashan

4

Recruitment center

Name of recruitment center

Greater Fin health center

Full name of responsible person

Abolfazl Afzali

Street address

Greater Fin_Above the bank

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

City

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

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Web page address

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

Street address

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Web page address

Person responsible for updating data

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Position

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Other areas of specialty/work

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Square

City

Shahroud

Postal code

Phone

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