

# 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*

+98 23 3239 5054

**Fax**

**Email**

ebrahimi@shmu.ac.ir

**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**

Shahroud University of Medical Sciences, Hafte-Tir  
Square

**City**

Shahroud

**Postal code**

**Phone**

+98 23 3239 5054

**Fax**

**Email**

Afzali.a1373@shmu.ac.ir

**Web page address**

## Person responsible for updating data

### 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**

Shahroud University of Medical Sciences, Hafte-Tir  
Square

**City**

Shahroud

**Postal code**

**Phone**

+98 23 3239 5054

**Fax**

**Email**

Afzali.A1373@gmail.com; Afzali.A1373@shmu.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr. Hussein Ebrahimi

**Position**

Ph.D. Nursing

**Other areas of specialty/work**

**Street address**

Shahroud University of Medical Sciences, Hafte-Tir  
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*