

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Effects of magnesium supplementation on insomnia in the elderly

#### Protocol summary

##### Summary

The current study is a randomized, double-blind, placebo-controlled trial to evaluate the effects of magnesium supplementation on insomnia in the elderly. Subjects consist of volunteers: range 60-75 years, with a clinical diagnosis of insomnia, dietary magnesium intake lower than 75% of RDA and total serum magnesium lower than 0.95 mmol/L. Reasons for the exclusion from the study is: body mass index higher than 35 kg/m<sup>2</sup>, history of psychiatric disorders, severe depression or recent stressful life events, alcohol or substance abuse, a trans-meridian flight during last 6 weeks, diuretics use and hormone replacement therapy, including renal failure, acute heart failure, restless legs syndrome and acute apnea. 46 subjects randomly will be allocated into the magnesium or the placebo group and receiving 250 mg magnesium oxide or placebo twice daily for 8 weeks. In order to evaluate the effect of supplementation, insomnia severity index, sleep time, total serum magnesium, serum renin, serum cortisol, serum melatonin will be measured at baseline and after the intervention period.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109057479N1**

Registration date: **2011-09-15, 1390/06/24**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-09-15, 1390/06/24

##### Registrant information

###### Name

Behnood Abbasi

###### Name of organization / entity

Shahid Beheshti university of medical sciences-  
National nutrition and food technology research insti

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8870 4487

##### Email address

b.abbasi@nnftri.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Research project of National nutrition and food technology research institute - Shahid Beheshti university of medical sciences

##### Expected recruitment start date

2011-09-23, 1390/07/01

##### Expected recruitment end date

2011-11-22, 1390/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effects of magnesium supplementation on insomnia in the elderly

##### Public title

Effects of magnesium on insomnia

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion Criteria: Willing to Cooperate; Age 60-75 years; Having Insomnia according to ISI and Sleep-log questionnaires; Dietary intake of Magnesium under 75% RDA; Serum Mg level under 0.95mmol/L. Exclusion Criteria: BMI higher than 35 kg/m<sup>2</sup>; Having alcohol or drug abuse; Having psychiatric disorders; Severe depression or recent stress; Having Transmeridian trip

during last 6 weeks; Not willing to cooperate; Using loop diuretics, Cyclosporine, Digoxin, Amphotericin, Hormone replacement therapy; Having renal diseases, acute heart failure, restless legs syndrome, acute Apnea; Not using Mg supplement or placebo

#### Age

From **60 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **46**

#### 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

Shahid Beheshti university of medical sciences

##### Street address

Velenjak Street, Shahid Chamran Highway.

##### City

Tehran

##### Postal code

1985717443

#### Approval date

2011-08-06, 1390/05/15

#### Ethics committee reference number

041400

## Health conditions studied

### 1

#### Description of health condition studied

Insomnia

#### ICD-10 code

F51.0

#### ICD-10 code description

A condition of unsatisfactory quantity and/or quality of sleep, which persists for a considerable period of time, including difficulty falling asleep, difficulty staying

asleep, or early final waking.

## Primary outcomes

### 1

#### Description

Insomnia severity index

#### Timepoint

Baseline and after the intervention period

#### Method of measurement

ISI questionnaire

### 2

#### Description

Sleep duration

#### Timepoint

Baseline and after the intervention period

#### Method of measurement

Sleeplog questionnaire

### 3

#### Description

Total Serum Magnesium

#### Timepoint

Baseline and after the intervention period

#### Method of measurement

Atomic absorption spectrophotometry

### 4

#### Description

Serum Cortisol

#### Timepoint

Baseline and after the intervention period

#### Method of measurement

ELISA

### 5

#### Description

Serum Renin

#### Timepoint

Baseline and after the intervention period

#### Method of measurement

ELISA

### 6

#### Description

Serum Melatonin

#### Timepoint

Baseline and after the intervention period

#### Method of measurement

ELISA

## Secondary outcomes

## 1

### **Description**

Total energy intake

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

24-hrs recall for 3-days

## 2

### **Description**

Carbohydrate intake

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

24-hrs recall for 3-days

## 3

### **Description**

Dietary Calcium intake

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

24-hrs recall for 3-days

## 4

### **Description**

Dietary potassium,k intake

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

24-hrs recall for 3-days

## 5

### **Description**

Dietary caffeine intake

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

24-hrs recall for 3-days

## 6

### **Description**

Weight

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

Scale

## 7

### **Description**

Physical activity

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

Physical activity questionnaire

## 8

### **Description**

Depression

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

SCL-90 questionnaire

## 9

### **Description**

Quality of life

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

GHQ-28

## 10

### **Description**

loose stool

### **Timepoint**

Baseline and after the intervention period

### **Method of measurement**

Asking

## **Intervention groups**

### 1

#### **Description**

Intervention group will receive 250 mg magnesium supplement tablets. Bid for 8 weeks.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group will receive 250 mg placebo tablets containing starch. Bid for 8 weeks.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Health center of

##### **Full name of responsible person**

Mrs.Parmar

##### **Street address**

Dastgheib St., Ostad Moeen Ave., Azadi Ave., Azadi Sq.

##### **City**

Tehran

### 2

#### **Recruitment center**

**Name of recruitment center**  
Amirkabir Cultural Center  
**Full name of responsible person**  
Mrs.Kaviani  
**Street address**  
Gheytarie St, Saba Ave, Shariati Ave.  
**City**  
Tehran

### 3

**Recruitment center**  
**Name of recruitment center**  
Salmand cultural center  
**Full name of responsible person**  
Mrs.Sharar  
**Street address**  
Khoshkbarchi St., 17 Shahrivar Avn., Imam Hossein Sq.  
**City**  
Tehran

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
National nutrition and food technology research institute - Shahid Beheshti university of medical sc  
**Full name of responsible person**  
Dr.M.H.Faraji  
**Street address**  
No.46, West Arghavan St., Farahzadi Blvd., Shahrake Gharb  
**City**  
Tehran  
**Grant name**  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
National nutrition and food technology research institute - Shahid Beheshti university of medical sc  
**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**  
National nutrition and food technology research

institute-Shahid Beheshti University of Medical Scie  
**Full name of responsible person**  
Behnood Abbasi  
**Position**  
M.Sc. Student  
**Other areas of specialty/work**  
**Street address**  
Velenjak Street, Shahid Chamran Highway  
**City**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 8870 4487  
**Fax**  
**Email**  
b.abbasi@nnftri.ac.ir  
**Web page address**

## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
National nutrition and food technology research institute-Shahid Beheshti University of Medical Scie  
**Full name of responsible person**  
Masud Kimiagar  
**Position**  
Professor  
**Other areas of specialty/work**  
**Street address**  
Velenjak Street, Shahid Chamran Highway  
**City**  
Tehran  
**Postal code**  
1985717443  
**Phone**  
+98 21 2212 4333  
**Fax**  
**Email**  
smkimiagar@yahoo.com  
**Web page address**

## Person responsible for updating data

**Contact**  
**Name of organization / entity**  
National nutrition and food technology research institute-Shahid Beheshti University of Medical Scie  
**Full name of responsible person**  
Behnood Abbasi  
**Position**  
M.Sc. Student  
**Other areas of specialty/work**  
**Street address**  
Velenjak Street, Shahid Chamran Highway  
**City**  
Tehran  
**Postal code**  
**Phone**  
+98 21 8870 4487

**Fax**

**Email**

b.abbasi@nnftri.ac.ir

**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*