Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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/m2, 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)

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Recruitment status

Recruitment complete

Funding source

Research project of National nutrition and food technology research institute - Shahid Beheshty 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/m2; 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 wakening.

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 caltural center
Full name of responsible person
Mrs.Sharar
Street address
Khoshkbarchi St., 17 Shahrivar Avn., Imam Hossein Sq.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National nutrition and food technology research institute - Shahid Beheshty university of medical sc
Full name of responsible person
Dr.M.H.Faraji
Street address
No.46, West Arghavan St., Farahzadi Blvd., Shahrake Gharb
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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 Beheshty 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

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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