Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of magnesium on depression and sleep quality and quality of life in postmenopausal women: a randomized controlled trial

Protocol summary

Study aim
Determining the effect of magnesium on depression, sleep quality and quality of life in postmenopausal women

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 88 postmenopausal women. Blocked randomization method will be used for randomization.

Settings and conduct
The present study is a double-blind randomized controlled trial (participant, researcher, outcome evaluator and data analyst will be unaware of the treatment received) that will be done in postmenopausal women referred to health centers of the city of Tabriz.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women who are 45 to 60 years old; Mild and moderate depression based on the Beck questionnaire; Diagnosis of inappropriate sleep quality based on the Pittsburgh questionnaire Exclusion criteria: Having other psychotic disorders; Having diseases such as kidney disease and gastrointestinal disease

Intervention groups
Intervention group: Participants (44 women) will receive magnesium tablets with a dose of 250 mg one a day with a glass of water for 12 weeks. Control group: The Participants (44 women) will receive the placebo tablets with the same order as the intervention group.

Main outcome variables
Depression, sleep quality and quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N75**
Registration date: **2022-12-10, 1401/09/19**
Registration timing: **prospective**
Last update: **2022-12-10, 1401/09/19**
Update count: **0**

Registration date
2022-12-10, 1401/09/19

Registrant information

Name
Mojgan Mirghafourvand

Name of organization / entity
Tabriz University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-21, 1401/09/30

Expected recruitment end date
2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of magnesium on depression and sleep quality and quality of life in postmenopausal women: a randomized controlled trial

Public title
The effect of magnesium on depression and sleep quality and quality of life in postmenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women who are 45 to 60 years old. At least one year has passed since their last period. Mild and moderate depression based on the Beck questionnaire (score 14 to 28) Diagnosis of inappropriate sleep quality based on the Pittsburgh questionnaire (scores 6 to 21)

Exclusion criteria:

Having other psychotic disorders such as schizophrenia and active delusions ,Insanity, Bipolar disease, Dementia according to the person's self-report or medical record Regular use of supplements and minerals, especially magnesium, in the last few months Having diseases such as kidney disease (the active role of the kidney in magnesium homeostasis) and myasthenia gravis (due to the aggravation of the disease by magnesium) and gastrointestinal disease (diarrhea is a common side effect of magnesium) according to the individual's statement or the medical record. Planned surgery within the next three months (due to the incomplete continuation of the treatment process) Using drugs that interfere with magnesium (drugs such as Eltrombopag, Baloxavir, Tetracycline, Marboxil, Demeclocycline, Doxycycline, Minocycline, Oxytetracycline) The existence of recent crises in life

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be assigned to two groups of intervention (recipient of magnesium pill) and control (recipient of placebo pill) by block randomization method with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer, and the magnesium and placebo will be placed in the same packages numbered sequentially.

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person not involved in the research.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Tabriz University of Medical Sciences

Street address

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2022-12-06, 1401/09/15

Ethics committee reference number

IR.TBZMED.REC.1401.812

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

2

Description of health condition studied

Sleep quality

ICD-10 code

G47.9

ICD-10 code description

Sleep disorder, unspecified

Primary outcomes

1

Description

Depression

Timepoint

Before the start of the intervention, one month after the start of the intervention, after the end of the intervention

Method of measurement
Beck depression questionnaire

2

Description
Sleep quality and its subdomains
Timepoint
Before the start of the intervention, one month after the start of the intervention, after the end of the intervention
Method of measurement
Pittsburgh Sleep Quality Questionnaire

Secondary outcomes

1

Description
Quality of life and its subdomains
Timepoint
Before the start of the intervention, after the end of the intervention
Method of measurement
Menopause Quality of Life (MENQOL) questionnaire

Intervention groups

1

Description
Intervention group: Each person will receive 90 magnesium tablets of 250 mg made by Galenus company for 12 weeks. One tablet will be taken daily with a glass of water.
Category
Treatment - Drugs

2

Description
Control group: Each person will receive 90 placebo tablets similar to magnesium tablets made by Galenus for a period of 12 weeks. One tablet will be taken daily with a glass of water.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers
Full name of responsible person
Maryam Alizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Participant data is confidential.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available