Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of adding magnesium supplement on depressive symptoms in patients with major depressive disorder treated with antidepressants (SSRI

Protocol summary

Study aim

Determining the effect of magnesium supplementation on improving depressive symptoms in patients with major depressive disorder treated with antidepressants (SSRIs)

Design

A clinical trial with a control group, parallel groups, two-way blind, randomized, phase 3 was performed on 48 patients and random table method was used for randomization.

Settings and conduct

The study was conducted in Golestan Hospital of Ahvaz after selecting patients with major depression. They were randomly divided into two groups. Intervention group was treated with selective serotonin inhibitors and magnesium supplement at a dose of 250 mg per day for 6 weeks. The control group was treated with selective serotonin inhibitors and placebo.Then, information was collected through Beck questionnaire and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria were patients with major depression based on DSM-S and according to the diagnosis of a psychiatrist over 18 years of age and having minimum education to read the questionnaire. Exclusion criteria include neurological disorders, alcohol and drug use over the past 6 months, active suicidal ideation, pregnancy and lactation, mental retardation, liver and kidney failure, receiving monooxidase inhibitors during the last 8 weeks, and a history of seizures. Also, the use of drugs that interfere with magnesium and the presence of uncontrolled diseases such as diabetes and high blood pressure and allergies to antidepressants or magnesium supplements are other parameters that cause patients to leave the study.

Intervention groups

The intervention group was treated with selective serotonin inhibitors with magnesium supplement at a dose of 250 mg per day for 6 weeks and the control group was treated with selective serotonin inhibitors with placebo for 6 weeks.

Main outcome variables

Depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200823048493N1**
Registration date: **2020-10-25, 1399/08/04**
Registration timing: **retrospective**

Last update: **2020-10-25, 1399/08/04**
Update count: **0**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name

Sousan Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3441 6074

Email address

dr.sadeghi_45@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date
2019-06-10, 1398/03/20
Actual recruitment end date
2020-09-10, 1399/06/20
Trial completion date
2020-10-21, 1399/07/30

Scientific title
The effect of adding magnesium supplement on depressive symptoms in patients with major depressive disorder treated with antidepressants (SSRI

Public title
The effect of magnesium supplementation in improving depressive symptoms in patients with major depressive disorder treated with antidepressants
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with major depression based on DSM-S and according to the diagnosis of a psychiatrist Age over 18 years Having minimum education to read the questionnaire
Exclusion criteria:
Neurological disorders Taking alcohol and drug use during the last 6 months Active suicidal thoughts Pregnancy and lactation Mental retardation Liver and kidney failure Receiving monooxidase inhibitors during the last 8 weeks History of seizures Taking magnesium-interfering drugs Presence of uncontrolled diseases such as diabetes and high blood pressure Allergy to antidepressants or magnesium supplements
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **48**
Actual sample size reached: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
We divided each referral into two groups using a randomized table. This table was a collection of numbers. We Considered number from 1 to 24 for intervention and numbers 25 to 48 for control. Then we toughed one of the numbers and moved in one of the preset directions and assigned the numbers to one of the groups. Thus, patients were completely randomly divided.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients did not know about prescription drugs (placebo and drug). Also, the researcher (the person who provided these drugs to the patients) did not know about the assignment of patients to placebo and drug.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahwaz University of Medical Sciences
Street address
Ahwaz University of Medical Sciences, Golestan Blvd, Ahwaz
City
Ahwaz
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Khouzestan
Postal code
61357-15794
Approval date
2020-02-24, 1398/12/05
Ethics committee reference number
IR. AJUMS. REC.1398. 917

Health conditions studied

1

Description of health condition studied
Major Depressive Disorder
ICD-10 code
F32.3
ICD-10 code description
Major depressive disorder, single episode, severe with psychotic features

Primary outcomes

1

Description
Depression
Timepoint
In weeks 0, 2, 4 6
Method of measurement
Via Beck Depression Inventory

Secondary outcomes

1

Description
Side effects such as diarrhea
Timepoint
6 weeks after intervention
Method of measurement
Through questions from the patient.

Intervention groups

1

Description
The intervention group was treated with selective serotonin inhibitors (sertraline, citalopram, fluoxetine and fluoxacin) along with magnesium supplement at a dose of 250 mg per day for 6 weeks.
Category
Treatment - Drugs

2

Description
The intervention group was treated with selective serotonin inhibitors (sertraline, citalopram,fluoxetine and fluoxacin) along with placebo per day for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Susan Sadeghi
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Golestan hospital, Golestan Street, Ahwaz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mehdi Ahmadi Moghadam
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Vice Chancellor for Research,Ahvaz University of Medical Sciences, Golestan Blvd, Ahwaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Susan Sadeghi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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
Participants' consent for publication must be available
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
No - There is not 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