# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Jul 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)

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+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
**Province**
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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ahmadi-m@ajums.ac.ir
**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**
Psychiatrics
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## Person responsible for updating data

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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