

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effect of supplementation of magnesium on serum Level of BDNF and depression status in patients with depression

#### Protocol summary

##### Study aim

The effect of magnesium supplements on serum brain-derived neurotrophic factor and depression status in patients with depression

##### Design

Controlled clinical trial, with parallel groups, blind two-sided, randomized

##### Settings and conduct

We selected 46 depressed patients referring to Zahedan Baharan Psychiatric Clinic and then divided them into two groups of intervention (23 patients) and control (23 people) using randomized random sampling. The intervention group received 500 mg magnesium oxide tablets daily (2 tablets 250 mg) and the control group also receives 2 placebo tablets (containing starch) for 8 weeks. The patients and the curative staff who provide the pills to patients do not have any information about the contents of the intervention

##### Participants/Inclusion and exclusion criteria

Entry requirements; all people with depression are diagnosed, Age range 20 to 60 years old. Exclusion conditions: schizophrenia; bipolar disorder; kidney disease; myasthenia gravis; gastrointestinal disease; surgery scheduled in the next three months; use of a drug that interferes with magnesium; acute heart failure.

##### Intervention groups

The intervention group received 500 mg magnesium oxide tablets daily (2 tablets 250 mg) and the control group also receives 2 placebo tablets (containing starch) for 8 weeks.

##### Main outcome variables

Depression; BDN; magnesium

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190317043084N1**

Registration date: **2019-03-26, 1398/01/06**

Registration timing: **prospective**

Last update: **2019-03-26, 1398/01/06**

Update count: **0**

##### Registration date

2019-03-26, 1398/01/06

##### Registrant information

###### Name

Maryam Afsharfar

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3392 7160

###### Email address

maryam.afshaar.1991@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-09-22, 1398/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of supplementation of magnesium on serum Level of BDNF and depression status in patients with depression

##### Public title

The effect of magnesium supplements on depression

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

People aged between 20-60 years old and whose depression is diagnosed by the relevant psychiatrist

### Exclusion criteria:

Schizophrenia Bipolar disorder kidney disease Myasthenia Graves Gastrointestinal disease Surgery scheduled in the next three months Use of a drug that interferes with magnesium Acute heart failure

## Age

From **20 years** old to **60 years** old

## Gender

Male

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **46**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Randomly with the help of random numbers

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The patients and the curative staff who provide the pills to patients do not have any information about the contents of the intervention.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

##### Street address

Dr. Hesabi Square, Zahedan Medical Science Campus

##### City

Zahedan

##### Province

Sistan-va-Balouchestan

##### Postal code

9816743463

#### Approval date

2019-02-03, 1397/11/14

#### Ethics committee reference number

IR.ZAUMS.REC.1397.513

## Health conditions studied

### 1

#### Description of health condition studied

Depression

#### ICD-10 code

F32, F33

#### ICD-10 code description

This block contains disorders in which the fundamental disturbance is a change in affect or mood to depression (with or without associated anxiety) or to elation. The mood change is usually accompanied by a change in the overall level of activity; most of

## Primary outcomes

### 1

#### Description

Depression Score in Beck Questionnaire

#### Timepoint

Before the intervention and two months after the intervention

#### Method of measurement

Beck Depression Inventory

## Secondary outcomes

### 1

#### Description

BDNF

#### Timepoint

Before the intervention and two months after the intervention

#### Method of measurement

Measuring with laboratory kit on blood sample

### 2

#### Description

Serum magnesium

#### Timepoint

Before the intervention and two months after the intervention

#### Method of measurement

Serum magnesium test

## Intervention groups

### 1

#### Description

Intervention group: consists of 23 depressed people who receive two tablets of magnesium oxid tablets daily after breakfast and one after dinner for 8 weeks, and after 8 weeks again, Beck Depression Test for Depression and Magnesium Serum Assay and BDNF for Measurement The state of magnesium and BDNF is performed.

#### Category

Treatment - Drugs

2

### Description

Control group: consists of 23 depressed people receiving twice daily placebo tablets that have the same shape and color as the original pill, receive one after breakfast and one after dinner for 8 weeks, and again after 8 weeks, Beck Depression Test Serum magnesium and BDNF depression tests are used to measure the magnesium and BDNF status.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Baharan Hospital

#### Full name of responsible person

Maryam Afsharfard

#### Street address

Imam Khomeini Street, Bahareh Psychiatric Hospital

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9819713955

#### Phone

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#### Email

baharanhospital@zaums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Dr. Noor Mohammad Bakhshani

#### Street address

Dr. Hassabi square, Medical Sciences Campus

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#### Province

Sistan-va-Balouchestan

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#### Phone

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#### Email

public@zaums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

#### Full name of responsible person

Maryam Afsharfard

#### Position

Student

#### Latest degree

Bachelor

#### Other areas of specialty/work

Nutrition

#### Street address

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ahwaz

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Zahedan University of Medical Sciences

#### Full name of responsible person

Mansour Shahraki

#### Position

Associate Professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Zahedan University of Medical Sciences

**Full name of responsible person**

Maryam Afsharfard

**Position**

Student

**Latest degree**

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**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available