

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)

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+98 61 3392 7160

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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

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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

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Imam Khomeini Street, Bahareh Psychiatric Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

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

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

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Person responsible for scientific inquiries

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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