

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of oral magnesium supplementation on improvement of depression in depressed patients with magnesium deficiency

Protocol summary

Summary

It's a double-blind, controlled study that is done in two stages. The first stage involved 600 depressed patients referred to the clinic of Yazd Khatamolanbiya. To verify serum magnesium levels in depressed persons. For this purpose we will select persons aged 20-60 years and don't suffer from disorders and such as diseases kidney, liver, heart, thyroid, bleeding disorders, and malignancies, degenerative disease and don't take dietary supplements and antidepressants and diuretics in recent 3 months. And didn't happen events include loss of job, divorce, death of close relatives' family members, and they happened to be in the past 3 months. Beck Depression questionnaire will be completed. Then those whose scores were between 18-35 ml of blood have taken and will be analyzed by the central laboratory of Yazd. Then, between them, 60 patients with hypomagnesaemia (serum magnesium less than 75 / 0 mmol per liter) will select and with random codes are divided into two groups .the intervention group give 2magnesium oxide tablets daily for 8 weeks and the control group give 2placebo tablets for 8 weeks. People who are don't take Over 20% of medication during study or have started taking supplements or change in the type and dose of their medicines may have to be excluded of this study. After 12 weeks of intervention, serum magnesium Beck will be measured in both groups for the extent complementary. After 12 weeks of intervention, serum magnesium will be measured in both groups to assess the effect of a dietary supplement.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013121015744N1**

Registration date: **2014-08-15, 1393/05/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-15, 1393/05/24

Registrant information

Name

Afsane Rajizadeh

Name of organization / entity

Shahid Sadooghi University of Medical Sciences and Health Services in Yazd

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Yazd University of Medical Sciences martyr

Expected recruitment start date

2014-01-20, 1392/10/30

Expected recruitment end date

2014-06-21, 1393/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral magnesium supplementation on improvement of depression in depressed patients with magnesium deficiency

Public title

The effect of magnesium supplementation on depression

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: people aged 20-60 years old and depression is diagnosed by a psychiatrist; not suffering from disorders and diseases of the kidney, liver, heart, thyroid, bleeding disorders and malignancies; non-degenerative disease autoimmune; non- autoimmune degenerative diseases; lack of central nervous system diseases; no history of mental illness; lack of food; lack of consumption of antidepressants and diuretics during the last 3 months pregnant and not lactating and non-events include loss of job; divorce; death of first-degree relatives in the past 3 months and have not participated in other research projects that self -reporting of this information will be recorded. Exclusion criteria: people who are not more than 20 % of the drug; while studying people who start taking a multivitamin and mineral supplement may have changed who have created the drug are.

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **600**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadooghi University of Medical Sciences and Health Services in Yazd, Iran

Street address

Educational Research Center, Imam Reza, Next to the Governor, Daneshjo BLV

City

Yazd

Postal code

8916189165

Approval date

2013-11-23, 1392/09/02

Ethics committee reference number

17/1/157228/پ

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

Timepoint

Before the intervention, and three months after intervention

Method of measurement

Beck Depression Inventory

2

Description

Serum magnesium

Timepoint

Three months after the intervention, but intervention

Method of measurement

Serum magnesium test

Secondary outcomes

1

Description

Diarrhea

Timepoint

Monthly

Method of measurement

Ask the patient

Intervention groups

1

Description

The intervention group included 30 depressed patients with hypo magnesiumia will give daily two tablets of magnesium oxide. They will take tablets after breakfast and after dinner for 8 weeks. after 8 weeks again of the Beck depression test to measure depression and the test Serum Magnesium is performed to assess the situation.

Category

Treatment - Drugs

2**Description**

The control group include of 30 depressed patients with hypo magnesium daily two tablets of placebo in terms of shape and color appearance similar to the magnesium tablet are a number after breakfast and one after dinner for 8 weeks. and after 8 weeks re-testing of the Beck depression test to assess depression and serum magnesium test is performed to measure magnesium status.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Specialty and subspecialty clinics Khatam Anbiya
Yazd

Full name of responsible person

Doctor H. Mozaffari Khosravi

Street address

Specialty and subspecialty clinics Khatam Anbiya,
opposite the Fire department, Taleghani Avenue,
Yazd

City

Yazd

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research Council (Research and Technology) of
Shahid Sadooghi University of Medical Sciences and
Hea

Full name of responsible person

Prof. Hassan Mozaffari Khosravi

Street address

Bahonar Square, Yazd

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Council (Research and Technology) of Shahid
Sadooghi University of Medical Sciences and Hea

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahid Sadooghi University of Medical Sciences and
Health Services in Yazd

Full name of responsible person

Prof. Hassan Mozaffari Khosravi

Position

PhD Nutrition, Research Assistant in Shahid Sadooghi
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Afsane Rajizadeh

Position

Graduate student in Nutrition and Health Sciences

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty