

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of oral magnesium supplementation on cognitive function, fatigue, depression, anxiety and serum levels of magnesium, BDNF, IL-6 and Superoxide Dismutase II in relapsing-remitting multiple sclerosis patients

Protocol summary

Study aim

Investigating the effect of oral magnesium supplementation on cognitive function, fatigue, depression, anxiety and serum levels of magnesium, BDNF, IL-6 and Superoxide Dismutase II in relapsing-remitting multiple sclerosis patients

Design

Clinical trial with placebo control group, with parallel groups, triple blind, randomized, on 58 MS patients, randomization with blocks of 4 using software

Settings and conduct

The place is the MS Research Center of Sina Hospital in Tehran; on relapsing relapsing MS patients; triple blind; Blinding, randomization and preparation of supplement cans are done by a trained person outside the study so that the participants, researchers and the statistician remain blind until the end of the analyses.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the individual's willingness to participate in the study; definite patients with relapsing-remitting MS based on the 2017 McDonald diagnostic criteria who are on file at Sinai Hospital; age range 18-55 years old; EDSS less than 5.5; education above diploma; more than one month has passed since the last corticosteroid injection (pulse therapy); more than one month has passed since the last relapse of the disease. Exclusion criteria: suffering from another neurological disease other than MS; pregnancy or breastfeeding; suffering from chronic gastrointestinal, liver, kidney, heart, respiratory and cancer diseases; having a diet for any reason; suffering from severe psychological disorders such as major depression History of allergy to Magnesium.

Intervention groups

Intervention group: Magnesium oxide supplement 750 mg in the form of three 250 mg tablets (TDS) for 12

weeks. Control group: placebo supplement, 750 mg of corn starch powder in the form of three 250 mg tablets (TDS) for 12 weeks.

Main outcome variables

Cognition; depression; anxiety; fatigue; serum levels of magnesium; BDNF; IL-6, and Superoxide Dismutase II

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220101053582N2**

Registration date: **2023-06-20, 1402/03/30**

Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Abdorrezza Naser Moghadasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 937 438 1919

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-21, 1402/04/30
Expected recruitment end date
 2024-02-19, 1402/11/30
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 Investigating the effect of oral magnesium supplementation on cognitive function, fatigue, depression, anxiety and serum levels of magnesium, BDNF, IL-6 and Superoxide Dismutase II in relapsing-remitting multiple sclerosis patients

Public title
 Investigating the effect of oral magnesium supplementation on cognitive function, fatigue, depression, anxiety of multiple sclerosis patients

Purpose
 Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The individual's willingness to participate in the study
 Definite patients with relapsing-remitting MS based on the 2017 McDonald diagnostic criteria (20) who are on file at Sinai Hospital Age range 18-55 years EDSS less than 5.5 Education above diploma More than one month has passed since the last corticosteroid injection (pulse therapy) More than one month has passed since the last relapse of the disease
Exclusion criteria:
 Suffering from another neurological disease other than MS Pregnancy or breastfeeding Suffering from chronic gastrointestinal, liver, kidney, heart, respiratory and cancer diseases Having a diet for any reason Suffering from severe psychological disorders such as major depression History of allergy to Magnesium

Age
 From **18 years** old to **55 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **58**

Randomization (investigator's opinion)
 Randomized

Randomization description
 People participating in the study are selected by easy sampling method. Patients are classified according to age and gender, and each person will be placed in the group receiving magnesium supplement or placebo using

random blocks of four with a ratio of 1:1. Blocks of four are randomly designed through the software, such as (ABAB), (BBAB), (AABB), (ABBA), (BAAB). Allocation of A or B to the supplement or placebo group will be done by a person outside of the research implementation, and the researchers will remain blind. Based on the list of prepared random blocks of four, a trained person outside the research team is responsible for randomly allocating patients. After the arrival of each patient, according to the 15 quadruple blocks prepared in the first stage, each patient will be randomly placed in group A or B, and the sample allocation process will be done consecutively until the end of sampling.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients are classified according to gender and each person will be placed in the group receiving magnesium supplement or placebo using block randomization of four with a ratio of 1:1. This study will be a triple-blind clinical trial, so participants, researchers, neurologists, and data analysts will be unaware that each patient is receiving magnesium supplements or placebo. In this method, one of the letters A or B will be assigned to each group, and for the purpose of blinding, this will be done by the manufacturer of the supplement and placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Neurorehabilitation Research Institute/MS R.C, Sinai Hospital

Street address

"Neural Rehabilitation" Neuroscience Research Institute, Imam Khomeini Hospital, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733139

Approval date

2023-06-11, 1402/03/21

Ethics committee reference number

IR.TUMS.NI.REC.1402.007

Health conditions studied

1

Description of health condition studied

Multiple Sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Cognition

Timepoint

At the beginning of the study and at the end of the 12th week

Method of measurement

MACFIMS test

2

Description

Anxiety

Timepoint

At the beginning of the study and at the end of the 12th week

Method of measurement

Beck Anxiety Inventory (BAI)

3

Description

Depression

Timepoint

At the beginning of the study and at the end of the 12th week

Method of measurement

Beck Depression Inventory (BDI)

4

Description

Fatigue

Timepoint

and at the end of the 12th week

Method of measurement

Fatigue Severity Scale (FSS) questionnaire

5

Description

Physical Activity

Timepoint

At the beginning of the study

Method of measurement

International Physical Activity Questionnaire (IPAQ)

6

Description

Magnesium level

Timepoint

At the beginning of the study and at the end of the 12th week

Method of measurement

Blood test

7

Description

BDNF level

Timepoint

At the beginning of the study and at the end of the 12th week

Method of measurement

Blood test

8

Description

IL-6 level

Timepoint

At the beginning of the study and at the end of the 12th week

Method of measurement

Blood test

9

Description

Superoxide Dismutase II activity

Timepoint

At the beginning of the study and at the end of the 12th week

Method of measurement

Calorimetry

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The duration of intervention in this clinical trial will be 12 weeks. Individuals receiving a magnesium supplement will receive 750 mg of magnesium per day in three 250 mg tablets (TDS).

Category

Rehabilitation

2

Description

Control group: The duration of intervention in this clinical trial will be 12 weeks. The control group will receive placebo with an equal amount of 750 mg of cornstarch powder daily in the form of three 250 mg dose tablets (TDS).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

MS research center, Sina hospital

Full name of responsible person

Abdorrezza Naser Moghadasi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr MohammadAli Sahraian

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Tehran University of Medical Sciences, Poursina St.,
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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ali Rezaei Ahvanouei

Position

Researcher

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abdorrezza Naser Moghadasi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for updating data

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Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

All information can be shared

When the data will become available and for how long

Beginning of the access period, 6 months after the
publication of the results

To whom data/document is available

for everyone

Under which criteria data/document could be used

no other conditions

From where data/document is obtainable

To the email address: abdorrezamoghadasi@gmail.com

What processes are involved for a request to access data/document

Send me an email

Comments