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
Abdorreza Naser Moghadasi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 937 438 1919

Email address
abdorrezamoghadasi@gmail.com

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
Abdorreza Naser Moghadasi
Street address
Imam Khomeini Street
City
Tehran
Province
Semnan
Postal code
1136749986
Phone
+98 21 6634 8571
Email
abdorrezamoghadasi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr MohammadAli Sahraian
Street address
Tehran University of Medical Sciences, Poursina St., 16th Azar St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1136749986
Phone
+98 21 6634 8571
Email
sahraian1350@yahoo.com

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
Street address
Tehran University of Medical Sciences, Poursina St., 16th Azar St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1136749986
Phone
+98 21 6634 8571
Email
alirezaeeii1375@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Abdorreza Naser Moghadasi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Tehran University of Medical Sciences, Poursina St., 16th Azar St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1136749986
Phone
+98 21 6634 8571
Email
abdorrezamoghadasi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Abdorreza Naser Moghadasi

Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Tehran University of Medical Sciences, Poursina St., 16th Azar St., Keshavarz Blvd.
City
Tehran
Province
Tehran
Postal code
1136749986
Phone
+98 21 6634 8571
Email
abdorrezamoghadasi@gmail.com

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