Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the effect of methylprednisolone pulse administration regimen on sleep quality in patients with multiple sclerosis admitted to Loghman Hakim Hospital in 2026

Protocol summary

Study aim
To determine and compare the effect of two methylprednisolone pulse administration regimens on sleep quality, insomnia severity, and cognitive function in patients with multiple sclerosis.

Design
Randomized, two arm, parallel group, non placebo, pretest and posttest clinical trial, phase 4, on 63 patients. Randomization will be performed using simple randomization.

Settings and conduct
The study will be conducted in the neurology ward of Loghman Hakim Hospital. After obtaining informed consent, patients will be allocated to one of the two groups, and sleep quality and cognitive function will be assessed before and after the intervention.

Participants/Inclusion and exclusion criteria
Patients with definite multiple sclerosis diagnosed by a neurologist, indication for methylprednisolone pulse therapy, age 18 to 99 years, and written informed consent will be included; patients with severe psychiatric disorders, use of sleep affecting medications, inability to complete questionnaires, or severe drug related adverse events will not be included.

Intervention groups
The first group will receive intravenous methylprednisolone 500 mg twice daily every 12 hours; the second group will receive intravenous methylprednisolone 1000 mg once daily.

Main outcome variables
Change in Insomnia Severity Index questionnaire score; change in Montreal Cognitive Assessment test score; change in Rey Osterrieth Complex Figure Test score.

General information

Reason for update

Acronym
MS-MP Sleep Trial

IRCT registration information
IRCT registration number: **IRCT20220803055606N4**
Registration date: **2026-06-03, 1405/03/13**
Registration timing: **prospective**

Last update: **2026-06-03, 1405/03/13**
Update count: **0**

Registration date
2026-06-03, 1405/03/13

Registrant information

Name
alireza moradi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 6522 4135
Email address
alirezamoradi_md@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-06-22, 1405/04/01

Expected recruitment end date
2026-07-23, 1405/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of methylprednisolone pulse administration regimen on sleep quality in patients with multiple sclerosis admitted to Loghman Hakim Hospital in 2026

Public title

Comparison of two methylprednisolone pulse regimens on sleep quality in patients with multiple sclerosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with definite diagnosis of multiple sclerosis confirmed by a neurologist, indication for methylprednisolone pulse therapy, age above 18 years, admission to the neurology ward of Loghman Hakim Hospital, and written informed consent will be included.

Exclusion criteria:

Severe psychiatric disorders, concomitant use of sleep-affecting medications such as benzodiazepines, inability or unwillingness to complete questionnaires, lack of informed consent, and severe drug-related adverse events requiring discontinuation of treatment.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each participant is a patient with multiple sclerosis who meets the eligibility criteria and has an indication for methylprednisolone pulse therapy. After obtaining written informed consent, each patient will be enrolled only once as one study sample/unit. Sleep quality and cognitive function assessments will be performed before and after the intervention; however, each participant will be considered as only one statistical unit.

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly allocated in a 1:1 ratio to one of the two treatment groups. The randomization sequence will be generated using a computer-generated random list or random number table. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study is designed as a randomized, two-arm, parallel-group clinical trial with a pre-test/post-test design. Both groups receive standard methylprednisolone pulse therapy, and the main difference between the groups is the dosing schedule. One group receives intravenous methylprednisolone 500 mg twice daily every 12 hours, while the other group receives 1000 mg once daily. Therefore, there is no placebo group, and the study aims to compare the effects of two active administration regimens on sleep quality and cognitive performance in patients with multiple sclerosis. Outcomes are assessed before treatment initiation and after completion of the intervention using the Insomnia Severity Index questionnaire, the Montreal Cognitive Assessment test, and the Rey Osterrieth Complex Figure Test.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine - Shahid Beheshti University of Medical Sciences

Street address

Next to Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1333635445

Approval date

2025-12-16, 1404/09/25

Ethics committee reference number

IR.SBMU.MSP.REC.1404.615

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

Change in Insomnia Severity Index questionnaire score

Timepoint

Before starting methylprednisolone pulse therapy and after completion of treatment

Method of measurement

The standard Insomnia Severity Index questionnaire includes 7 items with a score range from 0 to 28.

Secondary outcomes

1

Description
Change in global cognitive function score in patients with multiple sclerosis
Timepoint
Before starting treatment and after completion of the intervention
Method of measurement
Using the Montreal Cognitive Assessment test, with a score range from 0 to 30

2

Description
Change in visuospatial memory, planning, and cognitive organization score in patients with multiple sclerosis
Timepoint
Before starting treatment and after completion of the intervention
Method of measurement
Using the Rey Osterrieth Complex Figure Test through copying and recall of the complex figure

3

Description
Change in insomnia severity category in patients with multiple sclerosis, including normal status, mild insomnia, moderate insomnia, and severe insomnia
Timepoint
Before starting treatment and after completion of the intervention
Method of measurement
Using the Insomnia Severity Index questionnaire, including 7 items with a score range from 0 to 28; scores 0 to 7 are considered normal, 8 to 14 mild insomnia, 15 to 21 moderate insomnia, and 22 to 28 severe insomnia

Intervention groups

1

Description
Intervention group: Group 1: Patients in this group will receive intravenous methylprednisolone 500 mg twice daily every 12 hours, with a total daily dose of 1000 mg.
Category
Treatment - Drugs

2

Description
Intervention group: Group 2: Patients in this group will receive intravenous methylprednisolone 1000 mg once daily.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman Hakim Educational Hospital
Full name of responsible person
Dr. Mehrdad Roozbeh
Street address
Neurology Ward, Loghman Hakim Hospital, Kamali St, Lashgar Crossroads
City
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 5541 9005
Email
loghman.hospital@sbmu.ac.ir
Web page address
https://lhmc.sbmu.ac.ir/index.jsp?pageid=18901&p=1

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Afshin Zarghi
Street address
Velenjak, Shahid Chamran Highway, Yemen St, Shahid Arabi St, Next to Ayatollah Taleghani Hospital
City
Tehran
Province
Tehran
Postal code
1985717434
Phone
+98 21 2243 9781
Fax
Email
zarghi@sbmu.ac.ir
Web page address
https://research.sbmu.ac.ir/
Grant name
No specific grant
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyedeh Zahra Hashemi
Position
Student Investigator
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Neurology Ward, Loghman Hakim Hospital, Kamali St, Lashgar Crossroads
City
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 5541 9005
Email
hashemi.zahra.90@gmail.com
Web page address
https://lhmc.sbmu.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyedeh Zahra Hashemi
Position
Student Investigator
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Neurology Ward, Loghman Hakim Hospital, Kamali St, Lashgar Crossroads
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Phone
+98 21 5541 9005
Email
hashemi.zahra.90@gmail.com
Web page address
https://lhmc.sbmu.ac.ir/

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Seyedeh Zahra Hashemi
Position
Student Investigator
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
Street address
Neurology Ward, Loghman Hakim Hospital, Kamali St, Lashgar Crossroads
City
Tehran
Province
Tehran
Postal code
1333635445
Phone
+98 21 5541 9005
Email
hashemi.zahra.90@gmail.com
Web page address
https://lhmc.sbmu.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Due to the confidentiality of patients' clinical information and ethical restrictions regarding individual participant data, the individual participant dataset will not be publicly shared. Data will be analyzed in coded form, and only aggregate, non identifiable results will be published as a thesis or scientific article.
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Not applicable
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The study protocol, statistical analysis plan, and final study report may be shared through the academic thesis

and scientific publication. Individual participant data, informed consent forms, and the data dictionary will not be publicly shared.

When the data will become available and for how long

After completion of the study and publication of the scientific article, upon formal request and approval by the scientific investigator.

To whom data/document is available

Academic researchers, journal reviewers, regulatory authorities, and the ethics committee, upon formal request and approval by the scientific investigator.

Under which criteria data/document could be used

Shareable documents may be used only for scientific, educational, peer review, or future study design purposes. Any use must preserve confidentiality, prevent patient identification, and cite the original source.

From where data/document is obtainable

Requests should be submitted to the scientific investigator or the study investigator at Shahid Beheshti University of Medical Sciences.

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

Written requests will be reviewed by the scientific investigator, and if necessary, after approval by the ethics committee or the relevant university authority, limited access to shareable documents will be provided.

Comments

Raw individual patient data and identifiable participant information will not be shared.