Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Assessing the effect of Fampridine on cognitive outcome measures in multiple sclerosis patients: A double-blind, randomized, placebo-controlled study

Protocol summary

Study aim

Evaluating the effect of Fampridine on - cognitive function - gait function - upper limb function - walking disability self-rating - Expanded Disability Status Scale (EDSS) in Multiple Sclerosis patients Evaluating the relationship of EDSS score with response to Fampridine Evaluating the relationship of age and sex with response to Fampridine

Design

Phase III double-blinded placebo-controlled randomized trial of 108 patients enrolled between January 2024 and January 2025.

Settings and conduct

Patients are assessed by a neurologist or General practitioner in two hospital MS clinics in Tehran(Imam Khomeini and Imam Hussein hospital) and appropriate tests will be conducted. Patients, their caregivers, interviewer and medical personnel who are involved in the study are all blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: age between 18-60 years, definite Multiple sclerosis diagnosis based on 2017 McDonald criteria, SDMT score below the 20th percentile based on normative values, ability to perform motor tests without help of a person Exclusion criteria are: History of relapse within 2 months of first visit and during the study; History of seizure; History of Fampridine use within 1 month of first visit; moderate or higher renal dysfunction (GFR lower than 50 mL/min)

Intervention groups

Eligible patients receive appropriate instructions and give permission and consent to enroll in the study. They will be assessed in person at commencement and also after 12 weeks of getting placebo or Fampridine. During each visit, questionnaires and functional tests - cognitive and physical domains - will be completed accordingly. During the study patients will be contacted regularly and will be asked about drug side effects and their drug adherence.

Main outcome variables

Change in SDMT test score after 12 weeks of intervention

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161212031362N4**
Registration date: **2024-05-10, 1403/02/21**
Registration timing: **prospective**

Last update: **2024-05-10, 1403/02/21**
Update count: **0**

Registration date

2024-05-10, 1403/02/21

Registrant information

Name

Mohammad Hossein Harirchian

Name of organization / entity

Iranian center of neurological research

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-05-19, 1403/02/30

Expected recruitment end date

2025-01-09, 1403/10/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Assessing the effect of Fampridine on cognitive outcome measures in multiple sclerosis patients: A double-blind, randomized, placebo-controlled study

Public title
Evaluating the short-term effect of Fampridine on cognitive function in Multiple sclerosis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Definite MS diagnosis according to McDonald 2017 criteria Age between 18-60 years SDMT score below the 20th percentile of normative values
Exclusion criteria:
History of relapse within 2 months History of seizure/epilepsy History of major depression or psychosis Reluctance to enroll in the study Moderate or higher renal dysfunction (eGFR=< 50mL/min/1.73m2)
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **108**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of the study is achieved by block randomization of patients in to blocks of 12 (6 in Fampridine group and 6 in Placebo group) by Web-based Randomization. each space in any given block is given a code consisting of 3 random digits or letters (fk8 for example). These codes are written on the drug labels as well and are given to patients enrolled in the study. The study coordinators will use a list containing the order of these codes, and according to this list and in sequence of entry into the study, they will deliver the vial to the participants.
Blinding (investigator's opinion)
Double blinded
Blinding description
Study participants and other health care providers, including medical staff involved in the study, are blinded to the allocation of patients into either the Fampridine or placebo group. Medications and placebos are administered to patients by a clinical observer who remains unaware of the contents of the medication vials.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Neuroscience Institute , Tehran University of Medical Sciences
Street address
Neuroscience Institute, Imam Khomeini Hospital complex; Keshavarz Blvd
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Tehran
Postal code
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Approval date
2023-12-16, 1402/09/25
Ethics committee reference number
IR.TUMS.NI.REC.1402.041

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 (SDMT) Symbol Digit Modalities Test score (improvement of equal or greater than 4 points or more than 20% increase compared to baseline score is considered a meaningful change)
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
SDMT test which is scored based on the number of correct answers in 90 seconds

Secondary outcomes

1

Description
Change in California Verbal Learning Test (CVLT) test score
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
CVLT test

2

Description
Change in Brief Visuospatial Memory Test (BVMT) test score
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
BVMT test is performed three times consecutively and the sum of three scores is considered as total BVMT score

3

Description
Change in Twelve Item MS Walking Scale (MSWS-12) test score
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
MSWS-12 questionnaire

4

Description
Timed 25-Foot Walk (T25-FW) test score improvement
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
Timed 25-Foot Walk (T25-FW)

5

Description
Improvement in 9-Hole Peg Test (9-HPT) score
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
9-Hole Peg Test (9-HPT) is performed twice for each hand and mean of 4 tests is considered total score

6

Description
Modified Fatigue Impact Scale (MFIS) score change
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
Modified Fatigue Impact Scale (MFIS) questionnaire

7

Description
Change in Insomnia Severity Index (ISI) questionnaire score
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
Insomnia Severity Index (ISI) questionnaire

8

Description
Change in Hospital Anxiety and Depression Scale (HADS) score
Timepoint
First visit (baseline) and 12 weeks after intervention
Method of measurement
Hospital Anxiety and Depression Scale (HADS) questionnaire

Intervention groups

1

Description
Control group: Patients are given Placebo tablet for 12 weeks which is identical in shape and other physical characteristics as well as packaging. Drugs are instructed to be used every 12 hours, similar to the intervention group. Patients are instructed to take the tablet without food, on an empty stomach
Category
Placebo

2

Description
Intervention group: Patients are given Fampridine 10mg (Dalphyra, Cinnagen) for 12 weeks (instructed to be taken every 12 hours one in the morning and one in the afternoon). Patients are instructed to take the tablet without food, on an empty stomach.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital MS clinic
Full name of responsible person
Sadra Habibi Moini
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2

Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

empty

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iranian Center of Neurological Research

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

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

Sadra Hbibi Moini

Position

Research assistant

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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
Yes - There is 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
There is no further information

When the data will become available and for how long
The access period begins 6 months after publication of results.

To whom data/document is available
There is no further information

Under which criteria data/document could be used
There is no further information

From where data/document is obtainable
Email address: harirchm@sina.tums.ac.ir

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

Comments