Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Efficacy of Dalfyra (extended release Fampridine) in fatigue in multiple sclerosis patients

Protocol summary

Study aim
Determining and comparing the physical, cognitive and psychological aspects of fatigue between the intervention and control groups in patients with multiple sclerosis before and after receiving the drug and placebo

Design
In the form of randomised clinical Trial, with intervention and control groups. parallel group randomised trial with double blinded postoperative care and outcome assessment. Sample size of 44 people in each group

Settings and conduct
To patients in the first group, the drug Fampridine (with brand name Dalfyra) 10 mg is given twice daily and the other group is given a placebo (in the form of tablets by cinnagen). This study is double blind and the patient and the facilitator do not know the type of drug given .

Participants/Inclusion and exclusion criteria
Patients with MS over the age of 18 who have not taken Dalfira for the past year. Patients have not had an acute attack in the last 3 months. Patients have EDSS below 7. Patients are not allergic to the drug. Patients do not have a kidney problem or a history of seizures

Intervention groups
Fampridine(Dalfyra brand name) 10 mg (the pharmaceutical company Cinnagen) given to patients in the intervention group twice daily and placebo drug control (in pill form by Cinnagen) is given as same.

Main outcome variables
The physical aspect of MFIS (modified fatigue impact scale) ; Cognitive aspects of MFIS; The psychosocial aspect of MFIS MFIS total score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210429051129N1**
Registration date: **2021-06-07, 1400/03/17**
Registration timing: **prospective**

Last update: **2021-06-07, 1400/03/17**
Update count: **0**

Registration date
2021-06-07, 1400/03/17

Registrant information

Name
Shirin Mavandadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3332 6033

Email address
sh.mavandadi@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2021-09-23, 1400/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Dalfyra (extended release Fampridine) in fatigue in multiple sclerosis patients

Public title
Efficacy of Dalfyra (extended release Fampridine) in fatigue in multiple sclerosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with MS over the age of 18 who have not taken Dalfyra for the past year. Patients have The Expanded Disability Status Scale (EDSS) below 7

Exclusion criteria:

Patients have a kidney problem or a history of seizures. Patients who are allergic to this drug. Patients who have had an acute attack in the last 3 months.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Patients are divided into two treatment groups A and B using Balance block randomization method, the size of each block is 4 and the total number of blocks is 11. Balanced randomization allocation method for participants in a randomized controlled clinical trial study of the effect of receiving Dalfyra (group A) and placebo (group B) in reducing fatigue in patients with multiple sclerosis Randomization unit: individual Randomization tool: based on statistical software

Blinding (investigator's opinion)

Double blinded

Blinding description

These patients are divided into two groups based on random allocation: Dalfyra and placebo (11 blocks of 4). Patients in the first group are given famperidine, brand name Dalfyra 10 mg (from cinnagen Pharmaceutical Company) twice a day, and the other group is given a placebo (in the form of tablets by cinnagen Company). This study is double blind and the patient and the executor of the project do not know the type of drug given.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Qazvin University of Medical sciences

Street address

Qazvin University - Bahonar Blvd- Qazvin Town

City

Qazvin

Province

Qazvin

Postal code

1531534199

Approval date

2021-04-07, 1400/01/18

Ethics committee reference number

IR.QUMS.REC.1400.013

Health conditions studied

1

Description of health condition studied

Fatigue in patients with multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Multiple sclerosis

Primary outcomes

1

Description

Fatigue score based on modified fatigue impact scale (MFIS) questionnaire

Timepoint

Both groups complete the Fatigue score based on modified fatigue impact scale (MFIS) questionnaire at the beginning of the study and three months later

Method of measurement

Based on the Fatigue score based on modified fatigue impact scale (MFIS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group are given Famperidine (Delfyra 10 mg) (from Cinnagen Pharmaceutical Company) twice daily for three months.

Category

Treatment - Drugs

2

Description
Control group: The control group is given a placebo (in the form of tablets by Cinnagen Pharmaceutical Company) twice a day for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin Boali Hospital
Full name of responsible person
Shirin Mavandadi
Street address
Boali Educational and Medical Center, Boali Ave, Qazvin Town
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Email
boali.hospital@qums.ac.ir
Web page address
http://hosbooali.qums.ac.ir/Portal/Home/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr Mohammad mahdi Emamjomeh
Street address
Qazvin University of Medical Science Department of Research and Technology , Mavadat Street, Shahid Behesti Blvd, Qazvin Town
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+98 28 3333 7006
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memamjomeh@qums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
Qazvin University of Medical Sciences
Full name of responsible person
Shirin Mavandadi
Position
Resident
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Undecided - It is not yet known if there will be 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

Patient unidentifiable individuals data and the final clinical study report can be Released.

When the data will become available and for how long

Releasing after one year of publication of the study results

To whom data/document is available

Academic-scientific institutions

Under which criteria data/document could be used

The use of data and results is permitted for future scientific research.

From where data/document is obtainable

Receive data by email to the researcher shirin. mavandadi@yahoo.com sh.mavandadi@qums.ac.ir

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

About a month after sending the request

Comments