Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of the therapeutic efficacy and safety of dalfampridine on patients with Devic syndrome: A triple-blind randomized clinical trial study

Protocol summary

Study aim

1.Determining the efficacy and safety of Dalfampridine on patients with Devic syndrome 2.Determining and comparing the mean score of Timed 25-foot Walk in Devic patients 3.Determining and comparing the mean score of Lower Extremity Manual Muscle Test in Devic patients 4.Determining and comparing the mean score of the 12-item Multiple Sclerosis Walking Scale in Devic patients 5.Determining and comparing the mean scores of Quality of life, Fatigue, Depression and Anxiety in Devic patients

Design

The placebo group includes 35 patients with Devic, Assigned to this group randomly using table of random numbers treatment group with Dalfampridine includes 35 Devic patients, Assigned to this group with randomly using table of random numbers

Settings and conduct

The study was performed on patients with Devic referred to Isfahan Kashani Hospital in 1400. Patients, physicians visiting patients and statistical analyzers are blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 and 65 years, T25FW gait disorder: Test between 5 to 60 seconds, Definitive diagnose of Devic based on Wingerchuc criteria, No other neurological or psychological disorders, No relapse during the three months before the study Exclusion criteria: Patients with any drug side effects during the study such as seizures, kidney failure, anaphylaxis, etc., Patients whose disease worsens so he/she needs aggressive treatment, Unwillingness to cooperate During the study, Incomplete data or death of the patient ,Informed written dissatisfaction, Uncontrolled underlying disease (including kidney failure), Previous diagnose of multiple sclerosis and History of recurrent seizures

Intervention groups

Patients with Devic treated with Dalfampridine 10 mg Twice Daily

Main outcome variables

T25FW score; LEMMT score; MSWS-12 score;SF-36 score; Fatigue score;BDI score; BAI score; EDSS score;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210917052506N1**
Registration date: **2021-10-10, 1400/07/18**
Registration timing: **prospective**

Last update: **2021-10-10, 1400/07/18**
Update count: **0**

Registration date

2021-10-10, 1400/07/18

Registrant information

Name

shirin pourajam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3233 1062

Email address

shirinpourajam@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic efficacy and safety of dalfampridine on patients with Devic syndrome: A triple-blind randomized clinical trial study

Public title

Therapeutic effect of dalfampridine on patients with Devic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 16 to 65 years T25FW-based gait disorder: Test between 5 and 60 seconds Definitive diagnosis of Devic disease based on wingerchuc criteria No other neurological or psychological disease No relapse during the three months prior to enrollment

Exclusion criteria:

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After entering the study, patients were individually divided into two groups by simple random sampling using a table of random numbers. Then one of the two groups was randomly assigned to the intervention group by tossing coin, and the other group was named the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After completing the informed consent form and knowing how to work, patients are randomly assigned to the intervention and placebo groups without knowing the classified group. Visiting physicians also do not know which group the patient is in. Finally, the data analyzer analyzes the data according to the data collected by the researcher without knowing the data group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib st , Isfahan University of Medical Science

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2021-08-01, 1400/05/10

Ethics committee reference number

IR.MUI.MED.REC.1400.349

Health conditions studied

1

Description of health condition studied

Devic

ICD-10 code

G36.0

ICD-10 code description

Neuromyelitis optica [Devic]

Primary outcomes

1

Description

Timed 25-foot Walk score

Timepoint

The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week

Method of measurement

Examination by T25W table

2

Description

Lower extremity manual muscle test Score

Timepoint

The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week

Method of measurement

Examination by LEMMT table

3

Description
12-item Multiple Sclerosis Walking Scale Score
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
Examination by MSWS-12 table

4

Description
Quality of life score
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
Questionnaire SF-36

5

Description
Depression score
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
Questionnaire BDI

6

Description
Anxiety score
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
Questionnaire BAI

7

Description
Disability Status Scale (EDSS)
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
Examination, EDSS table

Secondary outcomes

1

Description
Quality of life score
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
Questionnaire SF-36

2

Description
Depression score
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
BDI Questionnaire

3

Description
Anxiety score
Timepoint
The first visit at the beginning of the study, the second visit in the seventh week, the third visit in the fourteenth week
Method of measurement
BAI Questionnaire

Intervention groups

1

Description
Intervention group: Patients in this group will receive dalfampridine (chemical compound 4-aminopyridine, FDA approved in MS patients, Nano Hayat Daru Co.) at a concentration of 10 mg twice daily. Then the patients' clinical symptoms and drug response will be evaluated in three visits at times of zero, seven and fourteen weeks.
Category
Treatment - Drugs

2

Description
Control group: Recieving placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Ayatollah Kashani Hospital
Full name of responsible person
Shirin Pourajam
Street address
Kashani St, Saheb Rozat St
City
Isfahan
Province

Isfehan
Postal code
818398343
Phone
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Email
dean@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shirin Pourajam
Street address
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Province
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8174673461
Phone
+98 31 3792 3071
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Shirin Pourajam
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Position
Resident
Latest degree
Medical doctor
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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data related to the participants will be accessible after being unidentified

When the data will become available and for how long

Access period starts six months after the results are published

To whom data/document is available

Doctors, Researchers

Under which criteria data/document could be used

The data will be available to improve patients' treatment or further research

From where data/document is obtainable

Dr Shirin Pourajam

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

Sending an email by the applicant including the details of the person and the reason for the request, review of the email by the executor of the project, if the request is confirmed, the data will be sent

Comments