Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the Efficacy of Dalfampridine on Walking Impairments in Acute Traumatic Cervical Spinal Cord Injury

Protocol summary

Study aim

Evaluation of the Effect of Dalfampridine on Walking Impairement of Patients with Acute Cervical Spinal Cord Injury

Design

Phase III Randomised, superiority, parallel group, triple blind trial on 30 patients. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site. https://www.sealedenvelope.com/simple-randomiser/v1/lists

Settings and conduct

In Shahid Kamyab, Shahid Hashemi Nejad, and Taleghani Hospitals of Mashhad, eligible patients will randomly enter into treatment and control groups. All patients receive high-dose methylprednisolone as standard treatment in the first 24 to 48 hours of trauma. The treatment group will take Dalfampridine 10 mg pill twice daily for two months. The control group will take placebo pill in parallel. The primary outcome variables will be measured in 3 times before, one and two months after treatment initiation. Patients will recieve the drug packages randomly, thus none of the participants, researchers, and Data and Safety Monitoring Committee will be aware of the process

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with traumatic cervical spinal cord injury; 2. Age between 18 and 70 years; 3. ASIA scale of C or D; 4. Glasgow Coma Scale of 15 Exclusion criteria: 1. Any History of Seizures in the Patient; 2. Any Contraindications for Dalfampridine Administration; 3. Pregnancy; 4. Glomerular Filtration Rate below 50

Intervention groups

In the treatment group, patients will take Dalfampridine 10 mg pills twice daily in the morning and evening for two months. The control group will also receive placebo pills for two months.

Main outcome variables

Disability Index; Dynamic Balance Test; Timed 25-Foot Walk Test; American Spinal Injury Association scale; Lower Extremity and Back Visual Analogue Scale; Oswestry Disability Index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231019059767N2**
Registration date: **2025-06-30, 1404/04/09**
Registration timing: **prospective**

Last update: **2025-06-30, 1404/04/09**
Update count: **0**

Registration date

2025-06-30, 1404/04/09

Registrant information

Name

Reza Bayat

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-07-06, 1404/04/15

Expected recruitment end date

2025-08-23, 1404/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the Efficacy of Dalfampridine on Walking Impairments in Acute Traumatic Cervical Spinal Cord Injury

Public title
Effect of Dalfampridine in Treatment of Spinal Cord Injury
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All Patients with Traumatic Cervical Spinal Cord Injury Patients with ASIA Scale C or D Patients without any Contraindications for Dalfampridine Prescription Patients having 18 to 70 Years of Age Patients who have GCS 15
Exclusion criteria:
Any History of Seizure in Patien Pregnancy Glomerular Filtration Rate Lower than 50 ml/min
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, blocking will be used as a reliable randomization method that leads to the balanced allocation of people in treatment groups at the end of each block. The website - https://www.sealedenvelope.com/simple-randomiser/v1/lists is used to prepare random blocks with variable sizes. The output of the site is such that, depending on the number of samples and the proposed sizes of the blocks, a specific number of blocks with different sizes (4 and 6) and with different sequences of block content is provided, which is followed by the content of each block in a sealed envelope. And when patients visit, one of the blocks is randomly selected and depending on the sequence of its content, the person in question is placed in one of the arms of the study. In the same way, after the completion of the first block, the second block is randomly selected and this continues until the last block and assigning the last person to the study arms. As a rule, by assigning the last sheet of the last block, the patients are grouped equally in the two arms of the study and the balance between the groups is established.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this thriple-blind study, patients will be divided into A and B groups through block randomization method. The drug and placebo are divided into two separate groups A and B by a person who is not involved in the study process. The contents of these two groups will remain in the sealed envelope until the end of the study. Within the first visit of the patient, a block will be randomly choosen. Based on the revealed content, patient will be included in group A or B and then will recieve his/her own corresponding drug. Dalfampridine and placebo tablets are both produced and packaged by the same company and completely similar in shape, color, smell and other characteristics. Also, the time and route of administration is similar. In this way, the participants, researcher, health personnel, data collectors, data evaluators, and the Safety and Data Monitoring Committee will not be aware of the allocation of patients to the study groups until end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Medicine-Mashhad University of Medical Sciences
Street address
Qoreishi building., Daneshghah Ave., Mashhad., Khorasan Razavi
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Postal code
9138813944
Approval date
2025-05-27, 1404/03/06
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1404.147

Health conditions studied

1

Description of health condition studied
Cervical Spinal Cord Injury
ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes

1

Description

Timed 25-Foot Walk Test

Timepoint

At the beginning of study (Before Treatment), 30, and 60 days after initiation of treatment

Method of measurement

Chronometer watch

2

Description

Dynamic Balance Test

Timepoint

At the beginning of study (Before Treatment), 30, and 60 days after initiation of treatment

Method of measurement

Chronometer watch

3

Description

Disability Index

Timepoint

At the beginning of study (Before Treatment), 30, and 60 days after initiation of treatment

Method of measurement

Disability Index Questionnare

4

Description

American Spinal Injury Association Impairment Scale

Timepoint

At the beginning of study (Before Treatment), 30, and 60 days after initiation of treatment

Method of measurement

American Spinal Injury Association Impairment Scale chart

5

Description

Oswestry Disability Index

Timepoint

At the beginning of study (Before Treatment), 30, and 60 days after initiation of treatment

Method of measurement

Oswestry Disability Questionnaire

6

Description

Lower Extremity Pain Visual Analogue Scale

Timepoint

At the beginning of study (Before Treatment), 30, and 60 days after initiation of treatment

Method of measurement

Visual Analogue Scale Diagram

7

Description

Back Pain Visual Analogue Scale

Timepoint

At the beginning of study (Before Treatment), 30, and 60 days after initiation of treatment

Method of measurement

Visual Analogue Scale Diagram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, patients after spinal cord injury receive routine high-dose Prednisolone treatment for 24 to 48 hours. Thereafter patients take Dalfampridine 10 mg tablets of Zist Orchid Pharmed company daily in the morning and evening for 2 months. In this way, the first dose is taken before breakfast and the second dose is taken 12 hours after that. The primary and secondary outcome variables are examined on 3 occasions including before the intervention, one month, and two months after the intervention. The content of Dalfampridine tablets includes 10 miligram of the main active ingredient Dalfampridine and other ingredients such as Hydroxypropyl methyl cellulose, Microcrystalline cellulose, Colloidal silicon dioxide, Magnesium stearate, Talc powder, and Sodium lauryl sulfate.

Category

Treatment - Drugs

2

Description

Control group: In the control group, patients after spinal cord injury receive routine high-dose Prednisolone treatment for 24 to 48 hours. After that, the patients take the placebo tablets prepared by Zist Orchid Pharmed company daily in the morning and evening for 2 months. In this way, the first dose is taken before breakfast and the second dose is taken 12 hours after that. The primary and secondary outcome variables are examined on 3 occasions before the intervention and one month and two months after the intervention. The content of the placebo tablets includes all the items of the main drug except the active ingredient Dalfampridine, which includes Hydroxypropyl methyl cellulose, Microcrystalline cellulose, Colloidal cilicon dioxide, Magnesium stearate, Talc powder, and Sodium lauryl sulfate.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Kamyab Hospital

Full name of responsible person
Ali Moghaddasi

Street address
Shahid Kamyab Hospital, Nakhrisi crossroad, Fadaeyan e Islam St, Mashhad, Khorasan razavi, Iran

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2

Recruitment center

Name of recruitment center
Shahid Hashemi Nejad Hospital

Full name of responsible person
Seyed Mohammad Mousavi

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3

Recruitment center

Name of recruitment center
Taleghani Hospital

Full name of responsible person
Saeide Sabagh Sajjadiye

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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

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Zist Orchid Pharmed

Proportion provided by this source
5

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

2

Sponsor

Name of organization / entity
Zist Orchid Pharmed

Full name of responsible person
Nassim Anjidani

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Tehran, District 3, Attar St, No. 42

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Email

Ask@orchidpharmed.com

Web page address

https://orchidpharmed.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zist Orchid Pharmed

Proportion provided by this source

95

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Babak Ganjeifar

Position

Associate professor

Latest degree

Specialist

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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available