Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

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

Protocol summary

Study aim

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

Design

Phase III Randomised, superiority, parallel group, triple blind trial on 52 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 Hospital 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 thoracic 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; 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: **IRCT20231019059767N1**
Registration date: **2024-01-17, 1402/10/27**
Registration timing: **prospective**

Last update: **2025-06-08, 1404/03/18**
Update count: **1**

Registration date

2024-01-17, 1402/10/27

Registrant information

Name

Reza Bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-20, 1402/10/30

Expected recruitment end date

2025-01-19, 1403/10/30

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 Thoracic 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 Thoracic 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 Patient Pregnancy GFR 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: **52**

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

City

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Razavi Khorasan

Postal code

9138813944

Approval date

2023-07-18, 1402/04/27

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1402.266

Health conditions studied

1

Description of health condition studied

Thoracic Spinal Cord Injury

ICD-10 code

T09.3

ICD-10 code description
Injury of spinal cord, level unspecified

Primary outcomes

1

Description
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

Secondary outcomes

1

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

2

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

3

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

4

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

5

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

6

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

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 before the intervention and 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
نسیم انجیدنی

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Tehran, District 3, Attar St, No. 42

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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

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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