Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 2026

Investigating the effectiveness of dalfampridine in improving spasticity in patients with severe brain trauma

Protocol summary

Study aim
Severity of muscle spasms

Design
This study is a three-blind randomized clinical trial that will be conducted in two treatment centers (Kashani and Al-Zahra) of Isfahan University of Medical Sciences. The studied population will be patients with severe brain trauma who refer to one of these two treatment centers and are hospitalized.

Settings and conduct
This study is a three-blind randomized clinical trial that will be conducted in two treatment centers (Kashani and Al-Zahra) of Isfahan University of Medical Sciences. The studied population will be patients with severe brain trauma who refer to one of these two treatment centers and are hospitalized. In fact, patients who have spasticity will be examined in the first six months after the trauma.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Being between 18 and 65 years old More than a month has passed since the beginning of the trauma Having a level of consciousness less than 9 Not having a neurological or psychological disease before the trauma Presence of spasticity in the upper or lower limbs according to the Ashworth criteria. Exclusion Criteria: Lack of consent of the patient's companion to enter the study Having a level of consciousness higher than 9 at the beginning of the trauma History of seizures, kidney and liver diseases

Intervention groups
Group 1: Dalfampridine receptor (this drug is prescribed to the patient at a dose of 10 mg twice a day (every 12 hours)) and will continue for 12 weeks. Group 2: placebo recipient (this drug is prescribed to the patient twice a day)

Main outcome variables
Severity of spasms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221108056446N2**
Registration date: **2023-05-08, 1402/02/18**
Registration timing: **prospective**

Last update: **2023-05-08, 1402/02/18**
Update count: **0**

Registration date
2023-05-08, 1402/02/18

Registrant information

Name
Mehdi Mahmoodkhani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 686 3733

Email address
mahmoodkhani@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-08-23, 1402/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effectiveness of dalfampridine in improving spasticity in patients with severe brain trauma

Public title

Dalfampridine in improving spasticity in patients with severe brain trauma

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being between 18 and 65 years old More than a month has passed since the beginning of the trauma Having a level of consciousness less than 9 Not having a neurological or psychological disease before the trauma Presence of spasticity in the upper or lower limbs according to the Ashworth criteria

Exclusion criteria:

Lack of consent of the patient's companion to enter the study Having a level of consciousness higher than 9 at the beginning of the trauma History of seizures, kidney and liver diseases

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

People are placed in 2 groups by random block method. In this way, the first 2 eligible people are selected and after obtaining consent, they enter to participate in the study. These 2 people are considered as a block of 2 and are sorted according to the last digit of the national code. The treatment methods are specified as A, B, and all combinations of 2 are specified, and after the last surgery, decoding is done for the last block.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In the random block method, people are divided into two groups, and then medication is administered by the clinical caregiver with a specific code for them, and it is provided to the researcher (student). The researcher evaluates the patients using a questionnaire and records the results based on the patient code. Patients are also not aware of the type of surgery. Also, the analyzer is not aware of the group in which the patient is placed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Isfahan University of Medical Sciences

Street address

Hazar Jarib Street, Azadi Square

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2022-02-05, 1400/11/16

Ethics committee reference number

IR.MUI.MED.REC.1400.784

Health conditions studied

1

Description of health condition studied

Severe traumatic brain injury

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

Primary outcomes

1

Description

Severity of muscle spasms

Timepoint

Before treatment, three and six months after the intervention

Method of measurement

Ashworth scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dalfampridine receptor (this drug is prescribed to the patient at a dose of 10 mg twice a day (every 12 hours))

Category

Treatment - Drugs

2

Description
Control group: Placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Mehdi Mahmoodkhani
Street address
Kashani Hospital
City
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83434-81839
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+98 31 3233 0091
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kashani@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
Street address
Hazar Jarib Street, Azadi Square
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81746-73461
Phone
+98 31 3668 0048
Email
mui@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
1
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
Esfahan University of Medical Sciences
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person
Mehdi Mahmoodkhani

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
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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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be 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