

# 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

Isfahan

##### 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**

Isfahan

**Province**

Isfahan

**Postal code**

83434-81839

**Phone**

+98 31 3233 0091

**Fax****Email**

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

**City**

Isfahan

**Province**

Isfahan

**Postal code**

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**

Neurosurgery

**Street address**

kashani street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

83434-81839

**Phone**

+98 31 3233 0091

**Email**

mahmoodkhani@mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehdi Mahmoodkhani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

Kashani street

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mehdi Mahmoodkhani

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

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83434-81839

**Phone**

+98 31 3233 0091

**Email**

mahmoodkhani@med.mui.ac.ir

## 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