

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Investigating the effect of using lumbar drain in patients with spinal cord injury

#### Protocol summary

##### Study aim

Improvement of sensory and motor disorders

##### Design

This study is conducted as a clinical trial without blinding, in which a lumbar drain is inserted in the case group, but it is not used in the control group. Patients are randomly divided into two groups in parallel groups. Randomizer software is used for randomization.

##### Settings and conduct

This study is conducted as a clinical trial without blinding, in which a lumbar drain is inserted in the case group, but it is not used in the control group. Patients are randomly divided into two groups in parallel groups. Randomizer software is used for randomization.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Patients who suffer severe spinal cord injury following trauma (according to Asian classification in groups A, B, and C) Consent to participate in the study. exclusion criteria: Age less than 18 years Lack of patient consent to enter the study No infection Penetrating trauma to the spine Having infiltrative diseases such as metastasis to the spine Presence of factors preventing MRI such as cardiac pacemaker Congenital disorders of the spine Previous history of spine surgery

##### Intervention groups

Case group: A drain is inserted for patients within the first 12 hours after referral and before performing lumbar surgery. Control group: patients are operated without lumbar drain insertion.

##### Main outcome variables

Sensory and motor disorders

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221108056446N3**

Registration date: **2023-07-27, 1402/05/05**

Registration timing: **prospective**

Last update: **2023-07-27, 1402/05/05**

Update count: **0**

##### Registration date

2023-07-27, 1402/05/05

##### 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

2023-08-23, 1402/06/01

##### Expected recruitment end date

2024-12-21, 1403/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of using lumbar drain in patients with spinal cord injury

##### Public title

lumbar drain in patients with spinal cord injury

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Patients who suffer severe spinal cord injury following trauma (according to Asian classification in groups A, B, and C) Consent to participate in the study.

**Exclusion criteria:**  
Age less than 18 years Lack of patient consent to enter the study No infection Penetrating trauma to the spine Having infiltrative diseases such as metastasis to the spine Presence of factors preventing MRI such as cardiac pacemaker Congenital disorders of the spine Previous history of spine surgery

**Age**  
From **18 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **30**

**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)**  
Not blinded

**Blinding description**

**Placebo**  
Not 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

2023-07-18, 1402/04/27

#### Ethics committee reference number

IR.MUI.MED.REC.1402.158

## Health conditions studied

### 1

#### Description of health condition studied

spinal cord injury

#### ICD-10 code

G95.8

#### ICD-10 code description

Other specified diseases of spinal cord

## Primary outcomes

### 1

#### Description

Sensory, motor disorder

#### Timepoint

Patients are examined one month, three months, six months and twelve months after lumbar drain placement.

#### Method of measurement

Clinical examination of the patient and force measurement of limbs

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For this group, a drain is inserted within the first 12 hours after referral and before lumbar surgery.

#### Category

Treatment - Devices

### 2

#### Description

Control group: Lumbar drain is not inserted in this group before surgery.

#### Category

Treatment - Devices

## 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

**Email**

kashani@mui.ac.ir

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

**Street address**

kashani street

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**Province**

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**Postal code**

83434-81839

**Phone**

+98 31 3233 0091

**Email**

mahmoodkhani@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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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

**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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Isafahan

**Province**

Isfahan

**Postal code**

83434-81839

**Phone**

+98 31 3233 0091

**Email**

mahmoodkhani@med.mui.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hamid Dashtian

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Neurosurgery

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**Email**

dashtian\_hamid@yahoo.com

## 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