

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

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Postal code

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Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asgari

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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

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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

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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