

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of the Effectiveness of Intravenous Infusion of Methylprednisolone 500 mg pulse with NSAIDs in lumbar disc herniation pain relief

#### Protocol summary

##### Study aim

To find out the effect of Methylprednisolone on disc herniation for patients referring to Imam Khomeini Hospital

##### Design

Two arm parallel group non randomized trial of 90 patients on phase 2-3

##### Settings and conduct

Methylprednisolone Sodium Succinate 500 mg pulse in 500 cc of Normal Saline intravenous infusion injection as a single dose for test group in injection site of Emam Khomeini Hospital's neurosurgery clinic . control group will receive no corticosteroid as pain killer . Patients's pain will be measured and recorded verbally and visually in first week and then monthly until 6 months

##### Participants/Inclusion and exclusion criteria

Patients above 18 with lumbar disc herniation visible in MRI and associated with low back pain radiating to lower limb that is lasting 6 months at least and there is no focal neurological defect

##### Intervention groups

Methylprednisolone Sodium Succinate 500 mg pulse in 500 cc of Normal Saline intravenous infusion injection as a single dose for test group in injection site of clinic and control group will receive no corticosteroid as pain killer but otc ones . patients are advise to rest in bed for 24h and the patients's pain will be measured and recorded verbally and visually in first week and then monthly until 6 months

##### Main outcome variables

low back pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20211116053077N1**

Registration date: **2022-01-30, 1400/11/10**

Registration timing: **prospective**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

##### Registration date

2022-01-30, 1400/11/10

##### Registrant information

###### Name

mohammad Abiri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 84 3222 7134

###### Email address

mohammadabiri7@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-01, 1400/11/12

##### Expected recruitment end date

2022-03-03, 1400/12/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the Effectiveness of Intravenous Infusion of Methylprednisolone 500 mg pulse with NSAIDs in lumbar disc herniation pain relief

## Public title

The effect of methylprednisolone pulse in patients with lumbar disc herniation

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Lumbar disc herniation visible in MRI Age above 18  
History of low back pain radiating to lower limb in last 6 months Filling out informed consent form

### Exclusion criteria:

Age under 18 Focal neurologic disorders existence  
History of vertebral surgery

## Age

From **18 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **90**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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

Ethics Committee of Ilam University of Medical Sciences

##### Street address

Ilam - Bangangab - Research Blvd.

##### City

ilam

##### Province

Ilam

##### Postal code

6939177143

#### Approval date

2021-10-23, 1400/08/01

#### Ethics committee reference number

IR.MEDILAM.REC.1400.152

## Health conditions studied

### 1

#### Description of health condition studied

Intervertebral disc disorders with radiculopathy, lumbar region

#### ICD-10 code

M51.16

#### ICD-10 code description

Intervertebral disc disorders with radiculopathy, lumbar region

## Primary outcomes

### 1

#### Description

Evaluation of pain relief in patients

#### Timepoint

The patient's condition is assessed one week after treatment, two weeks, three weeks, and one month and six months after treatment.

#### Method of measurement

MRI

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Methylprednisolone Sodium Succinate 500 mg (Lyomedrol EXIR) pulse in 500 cc of Normal Saline intravenous infusion injection as a single dose in 1 hour for test group . Patients will be advised to rest in bed for 24h and avoid heavy physical activities . patients will be taught wilson exercises to relieve their pain

#### Category

Treatment - Drugs

### 2

#### Description

Control group: There will be prescribed oral Diclofenac Sodium 100 mg (Alfen XL Alborz Darou) daily and Patients will be advised to rest in bed for 24h and avoid heavy physical activities . patients will be taught wilson exercises to relieve their pain

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Imam Khomeini Hospital  
**Full name of responsible person**  
Mohammad Abiri  
**Street address**  
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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Ilam University of Medical Sciences  
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Mohammad Reza Kafashian  
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info@medilam.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Ilam University of Medical Sciences

#### Proportion provided by this source

100

#### 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**  
Ilam University of Medical Sciences  
**Full name of responsible person**

Mohammad Abiri  
**Position**  
General Practitioner  
**Latest degree**  
Medical doctor  
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## Person responsible for scientific inquiries

#### Contact

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Associate professor  
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## Person responsible for updating data

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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