

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of sciatic nerve mobilization on pain, functional disability, sciatic nerve morphology and lower extremity muscles morphology in patients with lumbar radiculopathy due to disc herniation: A randomized controlled trial.

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of sciatic nerve mobilization technique and compare it with placebo treatment of sciatic nerve mobilization on pain indices, functional disability, sciatic nerve morphology and morphology of lumbar multifidus, biceps femoris, soleus and medial gastrocnemius muscles in patients with radiculopathy caused by disc bulging in lower back region.

##### Design

This study is a double-blind randomized controlled clinical trial with 46 participants.

##### Settings and conduct

Mobilization of sciatic nerve (nerve gliding technique) and placebo therapy on patients referred to the Faculty of Rehabilitation of Iran University. Participants and assessors are unaware of the group of people.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- 46 patients with radiculopathy in one leg for at least 3 months (having at least one of the symptoms: pain, numbness, tingling). 2- Age between 18-55 3-A positive SLR test at an angle of 20 to 70 degrees. 4- Body mass index less than 30 5- Pain level based on NPRS in the lower back during the last 24 hours at rest between 40 and 60 6- Confirmation of disc bulging using MRI at levels of L4-L5 and L5-S1. 7- Minimum reading and writing literacy in cycles. Exclusion criteria: 1- Absence of any underlying disease, including diabetes, previous problems, etc. 2- Any dissatisfaction and lack of participation of patients. 3- Low back pain due to rheumatoid arthritis, inflammation of the spine joints, infection, vertebral fracture, trauma, osteoporosis, etc. 4- Pregnancy 5- Physical therapy at least 1 month ago

##### Intervention groups

Intervention group: receiving basic treatment with sciatic

nerve mobilization Control group: Receiving basic treatment with placebo treatment of sciatic nerve mobilization

##### Main outcome variables

Pain, functional disability, SLR angle, morphology of sciatic nerve and nerve-giving muscles

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190315043058N3**

Registration date: **2024-03-29, 1403/01/10**

Registration timing: **prospective**

Last update: **2024-03-29, 1403/01/10**

Update count: **0**

##### Registration date

2024-03-29, 1403/01/10

##### Registrant information

##### Name

Ismail Ebrahimi Takamjani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-04-20, 1403/02/01  
**Expected recruitment end date**  
2024-12-20, 1403/09/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**

The effect of sciatic nerve mobilization on pain, functional disability, sciatic nerve morphology and lower extremity muscles morphology in patients with lumbar radiculopathy due to disc herniation: A randomized controlled trial.

**Public title**

The effect of sciatic nerve mobilization on pain, functional disability, sciatic nerve morphology and lower extremity muscles morphology in patients with lumbar radiculopathy due to disc herniation: A randomized controlled trial.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

46 patients with radiculopathy in one leg for at least 3 months (having at least one of the symptoms: pain, numbness, tingling) Age between 18-55 Positive SLR test at an angle of 20 to 70 degrees Pain score based on the NPRS scale in the lower back should be more than 40 and less than 60 during the last 24 hours at rest. BMI<30 Confirmation of disc bluging using MRI at levels of L4-L5 and L5-S1. Having a minimum reading and writing literacy (cycle) to fill out questionnaires.

**Exclusion criteria:**

Absence of any underlying disease, including diabetes, previous problems, etc. Any dissatisfaction and lack of participation of patients during the course of treatment. Low back pain due to rheumatoid arthritis, inflammation of the spine joints, infection, spondylolisthesis, fracture, trauma, osteoporosis, etc. pregnancy Physical therapy at least 1 month ago Any disease during the course of treatment that interferes with the research process. Injury to the limbs or back area during the course of treatment. Absence of more than 2 sessions during the course of treatment.

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **46**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

After completion of personal information and initial evaluations, patients with low back pain with radiculopathy symptoms will be randomly divided into two groups A or main treatment group: group B and control group receiving nerve mobilization placebo technique. Random allocation will be done in the variable block method, which consists of four-letter blocks made up of letters A and B. Then, the random list of treatments that will be obtained at the end of the assignment will be placed in the letters A and B in sealed and numbered envelopes (letter A represents nerve mobilization technique and the letter B represents the placebo technique of nerve mobilization). The random assignment process will be performed by an outside of the research team before the start of the study. After the initial evaluation by the examiner, the numbered envelopes will be presented to each person entering the study. Finally, after the patient enters the therapy sessions, the therapist will adjust the treatment interventions based on the letters in the envelope.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants will be given envelopes in a closed envelope before the start of the first treatment session, and one of the letters A or B is written. Attendees deliver envelopes to their therapist, only the therapist is allowed to open the envelopes. The evaluator does not know the groups of participants.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Iran university of medical sciences

**Street address**

Hemmat Highway., next to Milad Tower Iran  
University of Medical Sciences

**City**

Tehran

**Province**

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**Postal code**

1341853347

**Approval date**

2024-03-11, 1402/12/21

**Ethics committee reference number**

IR.IUMS.REC.1402.1167

## Health conditions studied

### 1

#### Description of health condition studied

patients with lumbar radiculopathy due to disc herniation

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Measurement of pain is done at the beginning of the study (before the intervention) and the last treatment period.

#### Method of measurement

Numeric pain rating scale (Moderate back pain in the last 24 hours at rest)

### 2

#### Description

Functional disability

#### Timepoint

Measurement of pain is done at the beginning of the study (before the intervention) and the last treatment period.

#### Method of measurement

Persian version of Oswestery disability index

### 3

#### Description

Straight leg raise Angle

#### Timepoint

Measurement of pain is done at the beginning of the study (before the intervention) and the last treatment period.

#### Method of measurement

Goniometer

## Secondary outcomes

### 1

#### Description

Changes in Sciatic Nerve Morphology

#### Timepoint

At the beginning of the study (before the intervention) and immediately after the last treatment session

#### Method of measurement

Ultrasonography devices

### 2

#### Description

Morphological Changes in Lower Extremity Muscles

#### Timepoint

At the beginning of the study (before the intervention) and immediately after the last treatment session

#### Method of measurement

Ultrasonography devices

## Intervention groups

### 1

#### Description

Intervention group: Mobilization of the sciatica nerve (gliding)

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Electrotherapy will consist of 20 minutes of conventional TENS (parameters include frequency 80-100 Hz; pulse width 50-100 microseconds; Flow Mode: Continuous; Patient Sense: Tingling within the patient's tolerance range).

#### Category

Treatment - Other

### 3

#### Description

Control group: Shame sciatic nerve mobilization techniques (nerve gliding)

#### Category

Placebo

### 4

#### Description

Control group: Electrotherapy will consist of 20 minutes of conventional TENS (parameters include frequency 80-100 Hz; pulse width 50-100 microseconds; Flow Mode: Continuous; Patient Sense: Tingling within the patient's tolerance range).

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Physiotherapy Clinic of Faculty of Rehabilitation Sciences, Iran University of Medical Sciences

##### Full name of responsible person

Maryam Ahmadi

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##### Province

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## Sponsors / Funding sources

### 1

#### Sponsor

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**Full name of responsible person**

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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**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Esmaeel Ebrahimi Takamjani

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

#### Contact

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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**

Not applicable

### **Data Dictionary**

Not applicable