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

Tehran

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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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 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