

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the effect of neurodynamic mobilization and dry needling techniques on the pain, function, and ankle range of motion in patients with lumbar herniated disc

Protocol summary

Study aim

The present study is designed to compare of the effect of neurodynamic mobilization and dry needling technique on the pain, function, and ankle range of motion in subjects with patients with lumbar herniated disc.

Design

A clinical trial with a control group, double-blind, randomized, is performed on 80 patients. Block randomization is used for randomization.

Settings and conduct

Patients with lumbar herniated disc are assigned to four groups of control, DN, neurodynamic, and a combination of these two techniques according to block randomization. The two-blind study will be conducted in such a way that people are assigned to groups and patients are evaluated by people who are unaware.

Participants/Inclusion and exclusion criteria

Patients aged 21-50 years who have been diagnosed with a disc lesion by MRI and a specialist physician. They also have pain, numbness, and tingling in the sciatic nerve path for at least 12 weeks to 1 year. In addition, they have a positive Slump and SLR test with neurological symptoms, are included in the study. Patients with lumbar canal stenosis or piriformis syndrome, any spinal surgery and any systemic disease and/or history of vertebral fracture or trauma were excluded from the study.

Intervention groups

Dry needling (DN): It is used on the trigger point in the lumbar, gluteal, thigh and leg muscles. The needle is applied for three sessions with an interval of one day. Neurodynamic technique: The technique of neurodynamic mobilization of the sciatic nerve is performed in two tension and slide modes three sessions a week for 2 weeks. Control group: After the involved points are determined, the therapist applied soft and superficial massage on the involved muscles.

Main outcome variables

1. Pain intensity 2. Disability index 3. Ankle range of motion

General information

Reason for update

Acronym

lumbar herniated disc(LHD)

IRCT registration information

IRCT registration number: **IRCT20240211060958N3**

Registration date: **2024-12-31, 1403/10/11**

Registration timing: **prospective**

Last update: **2024-12-31, 1403/10/11**

Update count: **0**

Registration date

2024-12-31, 1403/10/11

Registrant information

Name

tahereh rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3132 5367

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-02-08, 1403/11/20

Expected recruitment end date

2025-06-20, 1404/03/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of neurodynamic mobilization and dry needling techniques on the pain, function, and ankle range of motion in patients with lumbar herniated disc

Public title
Comparison of the effect of neurodynamic mobilization and dry needling techniques in patients with lumbar herniated disc

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All participants are aged from 21 to 50 years A disc lesion is diagnosed with confirmation from an MRI and a specialist. Complaints of pain , numbness, and tingling along the path of the sciatic nerve for at least twelve weeks to a year and not having acute pain in the last 4 weeks Positive Slump and SLR tests with neurological symptoms. Having functional disabilities including lifting objects or walking.
Exclusion criteria:
Patients with sciatica due to other pathologies, such as lumbar canal stenosis or piriformis syndrome. After any spinal surgery, for example, unilateral hemilaminectomy or microdiscectomy. Patients with a negative Slump test and progressive neurological symptoms, e.g. hyperexcitability and instability. History of fracture or trauma to the vertebrae. Systemic disorder, for example diabetes.

Age
From **21 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **20**
20 subjects per group

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization: A table of random numbers is used. Participants are given a number and using the table of random numbers. Therapist randomly starts from a table point in the row or column direction. The therapist can close his eyes and choose a point.

Blinding (investigator's opinion)
Double blinded

Blinding description
Double-blind study will be done, in this way, the allocation of people to the groups and the assessment of patients are done by people who are unaware of the status of the grouping of patients. Treatment is provided by a specialist physiotherapist and evaluated by a collaborator.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the kerman University of Medical Sciences

Street address

Haft Bagh Square, Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2024-10-09, 1403/07/18

Ethics committee reference number

IR.KMU.REC.1403.284

Health conditions studied

1

Description of health condition studied

lumbar disc herniation

ICD-10 code

M99.73

ICD-10 code description

Connective tissue and disc stenosis of intervertebral foramina of lumbar region

Primary outcomes

1

Description

Pain intensity

Timepoint

Before, After and 1month follow up

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Functional index

Timepoint

Before, After and 1month follow up

Method of measurement

Oswestry Disability Index, Roland–Morris Disability and Quebec Back Pain Disability Scale questionnaires

2

Description

Ankle range of motion

Timepoint

Before, after and 1month follow up

Method of measurement

Goniometer

Intervention groups

1

Description

Intervention group: Dry needling. The treatment is done in 3 sessions with an interval of one day. The muscles selected for dry needling in this study are practically important in the management of lumbar disc herniation, including: quadratus lumborum, paraspinal, multifidus, gluteus maximus, gluteus medius, gluteus minimus, iliopsoas, piriformis, hamstrings, and gastrocnemius.

Category

Rehabilitation

2

Description

Intervention group: Neuromobilization of sciatic nerve
The patient is placed in a sidelying position on the side of the healthy leg. The lower limbs are placed at a neutral hip position and 90 knee flexion. The trunk is in a straight position and the head is in a neutral position. The therapist stands behind the patient at the level of the pelvis so that the pelvis does not move forward or backward. Then, we ask the patient to move from a position of neck and trunk extension, knee flexion, and ankle plantar flexion to a position of neck and trunk flexion, knee extension, and ankle dorsiflexion, and vice versa.

Category

Rehabilitation

3

Description

Control group: While the patient is supine position, the therapist applies soft and superficial massage on the involved muscles. The fingertips of each therapist's hand are placed in contact with the related muscles and a surface massage is performed. The number of sessions is

the same as the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers affiliated to Kerman University of Medical Sciences

Full name of responsible person

Majid Ashraf Ganjavi

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Tehran Road, under the railway bridge, Red Crescent Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Hamid Sharifi

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The beginning of Haft Bagh Alavi axis, Kerman University of Medical Sciences campus

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sharifhami@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

tahereh rezaeian

Position

Assistant Professor of Kerman University of Medical Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Some of the data, such as information about the consequences, can be shared.

When the data will become available and for how long

Starting the access period: 6 months after publication the results.

To whom data/document is available

Researchers working in academic institutions.

Under which criteria data/document could be used

Only statistical analyses can be used to find treatment for improvement of patients.

From where data/document is obtainable

Applicants can be guided by email to the authors(tahere.rezaiyan@gmail.com).

What processes are involved for a request to access

data/document

First, they will email the authors of the study and we Will

be answered within a week.

Comments