Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of dry needling of the Medius and Hamstring muscles with the sciatic nerve neurodynamic technique on pain and nervous system mobility in people with chronic non-specific low back pain: A randomized (controlled) clinical trial

Protocol summary

Study aim

To compare the effects of dry needling of the gluteus medius and hamstring muscles, neurodynamic techniques, and their combination on referred pain intensity in the posterior lower limb, functional disability, and range of motion during the straight leg raise (SLR) test in patients with chronic nonspecific low back pain.

Design

A three-arm, parallel-group, randomized clinical trial with allocation concealment and blinded outcome assessment and data analysis in 30 patients with chronic nonspecific low back pain.

Settings and conduct

Patients referred by neurologists, orthopedic specialists, or physical medicine and rehabilitation specialists will be screened for eligibility. After informed consent, demographic and medical data will be collected, and 30 participants will be randomly allocated to three intervention groups (10 per group). Outcomes will be assessed at baseline, after 10 treatment sessions, and at one-month follow-up. The outcome assessor and statistical analyst will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Age 18–65 years; chronic nonspecific low back pain lasting more than 3 months; VAS pain score of 3–7 and Oswestry Disability Index (ODI) score >20%; SLR test at 40°–70°; active trigger points in the gluteus medius and hamstring muscles; absence of musculoskeletal, neurological, systemic, serious internal diseases; no history of fractures or lumbar or symptomatic lower-limb surgery; no physiotherapy or dry needling of the target muscles within the previous 6 months; and no pregnancy.

Intervention groups

Patients will be randomly allocated in a 1:1:1 ratio to three groups of 10 participants each: a neurodynamic group, a dry needling group, and a combined neurodynamic and dry needling group.

Main outcome variables

Pain intensity measured using the VAS, functional disability measured using the ODI, SLR range of motion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180925041138N3**
Registration date: **2026-10-26, 1405/08/04**
Registration timing: **prospective**

Last update: **2026-10-26, 1405/08/04**
Update count: **0**

Registration date

2026-10-26, 1405/08/04

Registrant information

Name
Jalal Ahadi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-11-22, 1405/09/01

Expected recruitment end date
2027-05-22, 1406/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effects of dry needling of the Medius and Hamstring muscles with the sciatic nerve neurodynamic technique on pain and nervous system mobility in people with chronic non-specific low back pain: A randomized (controlled) clinical trial

Public title
Dry Needling and Neurodynamic Techniques in Nonspecific Low Back Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Chronic Nonspecific Low Back Pain with Referred Pain to the Posterior Lower Limb Lasting More Than 3 Months Pain intensity ranging from 3 to 7 on a 10-cm Visual Analog Scale (VAS) An Oswestry Disability Index (ODI) score of >20% A positive Straight Leg Raise (SLR) test between 40° and 70° Presence of active myofascial trigger points in the gluteus medius and hamstring muscles
Exclusion criteria:
Presence of myopathy, neuropathy, or myelopathy Presence of systemic, inflammatory, or degenerative diseases History of trauma to the lumbopelvic region, lumbar surgery, or surgery involving the symptomatic lower limb History of arthroplasty or fracture involving the symptomatic lower limb Diagnosis of fibromyalgia Cognitive impairment affecting the ability to understand instructions or participate in the study History of physiotherapy, dry needling or injection targeting the gluteus medius and hamstring muscles within the previous 6 months Presence of serious medical conditions, including severe cardiopulmonary diseases or malignancies Severe needle phobia or any contraindication to dry needling History of substance abuse or current use of corticosteroid medications Pregnancy
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 30 eligible patients will be randomly allocated to three groups of 10 participants each: a neurodynamic technique group, a dry needling group, and a combined neurodynamic technique and dry needling group, using block randomization with an allocation ratio of 1:1:1. The individual participant will be the unit of randomization. The random allocation sequence will be generated using statistical software with variable block sizes to maintain balance in the number of participants across the three groups. The generated random allocation sequence will serve as the basis for assigning each participant to an intervention group. To ensure allocation concealment, the allocation sequence will be placed in sequentially numbered, opaque, sealed envelopes. The envelopes will be opened in numerical order only after each participant's eligibility has been confirmed and their enrollment has been finalized, thereby preventing the group allocation from being anticipated in advance.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, both the outcome assessor and the data analyst will be blinded to group allocation.
Placebo
Not used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Faculty of Rehabilitation Sciences, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665813
Approval date
2026-10-05, 1405/07/13
Ethics committee reference number
TBZMED.REC.1405.482

Health conditions studied

1

Description of health condition studied

Chronic non-specific Low Back Pain

ICD-10 code

M54.5

ICD-10 code description

Low back pain

Primary outcomes

1

Description

Referred pain intensity in the posterior thigh

Timepoint

Pain intensity will be measured at baseline, after the 10th session (immediately after completion of the intervention), and one month after completion of the intervention.

Method of measurement

Pain intensity will be assessed using the Visual Analogue Scale for Pain. This instrument consists of a 10-centimeter line, with one endpoint representing no pain and the other representing the worst imaginable pain.

Secondary outcomes

1

Description

Low back pain-related functional disability

Timepoint

At baseline, after tenth session (completion of the treatment) , and one month after completion of the intervention.

Method of measurement

using the Oswestry Disability Index questionnaire and expressed as a percentage of the total score

2

Description

Passive range of motion during the straight leg raise test

Timepoint

At baseline and after tenth session (completion of the treatment)

Method of measurement

using a goniometer

Intervention groups

1

Description

Intervention group: Including routine physiotherapy treatment and dry needling

Category

Rehabilitation

2

Description

Intervention group: Including routine physiotherapy treatment, neurodynamic techniques, and dry needling

Category

Rehabilitation

3

Description

Control group: Including routine physiotherapy treatment, neurodynamic techniques

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Physiotherapy Department, Nikan Clinic

Full name of responsible person

Bahram Amirshakeri

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Bahram Amirshakeri

Position

Associate 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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study Protocol: Effects of Dry Needling, Neurodynamic Techniques, and Their Combination in Patients with Chronic Nonspecific Low Back Pain. The document describes the study objectives, design, participant eligibility criteria, interventions, outcome measures, and assessment schedule. It will be made available upon reasonable request to the corresponding author after publication of the main study results, subject to applicable institutional and ethical requirements.

When the data will become available and for how long

The study protocol will be available upon reasonable request starting from the date of publication of the main study results and will remain available indefinitely, subject to applicable institutional and ethical

requirements.

To whom data/document is available

The study protocol will be available to researchers and other individuals affiliated with academic institutions, research organizations, or other relevant organizations, upon reasonable request to the corresponding author.

Under which criteria data/document could be used

Requests to access the study protocol should specify the intended research or academic purpose. Requests will be reviewed by the corresponding author to ensure that the proposed use is appropriate and consistent with applicable institutional and ethical requirements. The protocol may be used for academic, educational, or research purposes, provided that the document is appropriately cited and is not misrepresented.

From where data/document is obtainable

Researchers interested in obtaining the study protocol should contact the corresponding author by email. Requests should include the applicant's name, institutional affiliation (if applicable), and intended purpose of use. The corresponding author's contact details will be provided in the published study report or can be obtained through the study registration record in IRCT.

What processes are involved for a request to access data/document

Applicants should submit their request by email to the corresponding author, stating their name, institutional affiliation (if applicable), and intended purpose of use. The corresponding author will review the request and, if approved, provide the study protocol electronically by email. Requests will normally be reviewed within 14 working days, and the document will be provided within 30 working days of approval, subject to applicable institutional and ethical requirements.

Comments