Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Levator Scapulae Muscle Dry needling on Clinical Symptom in Patients with Cervical Radiculopathy: A Single Blind Randomized Controlled Trial

Protocol summary

Study aim
Effect of Levator Scapulae Muscle Dry needling on Clinical Symptom in Patients with Cervical Radiculopathy

Design
A Single Blind Randomized Controlled Trial

Settings and conduct
Participants in the control group will receive routine physiotherapy interventions for cervical radiculopathy. Those in the intervention group will receive dry needling therapy for the levator scapulae muscle, in addition to routine treatments. Outcome measures will be evaluated in both groups. Finally, all data will be statistically compared and analyzed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Individuals medically diagnosed with radiculopathy and experiencing neck pain radiating to one of the upper limbs. Age range between 18 and 55 years. Neck and upper limb pain intensity between 3 and 8 based on the NRS (Numerical Rating Scale). At least one month has passed since symptom onset. Presence of an active trigger point in the affected levator scapula muscle, diagnosed by a physiotherapist. Exclusion criteria: History of previous neck surgery. History of malignancy in the cervical or thoracic region. Skin disorders in the neck and shoulder area. Fear of needles. Lack of cooperation during treatment. Presence of cognitive impairment. Previous neurological injuries in the upper limb. Hyperreflexia. Diagnosis of myelopathy. History of trauma to the neck, thoracic, or shoulder area.

Intervention groups
Participants in this study will be randomly assigned to either the intervention or control group. Individuals in the control group will receive routine physiotherapy interventions for cervical radiculopathy. Participants in the intervention group will receive the same routine physiotherapy treatments, but in addition, they will undergo dry needling therapy for the levator scapulae muscle during the third, sixth, and ninth sessions.

Main outcome variables
Pain Intensity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200215046499N5**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **prospective**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date
2025-05-29, 1404/03/08

Registrant information

Name
Hakimeh Adigozali

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-05, 1404/04/14

Expected recruitment end date
2026-05-04, 1405/02/14

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of Levator Scapulae Muscle Dry needling on Clinical Symptom in Patients with Cervical Radiculopathy: A Single Blind Randomized Controlled Trial

Public title
Effect of Levator Scapulae Muscle Dry needling
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals medically diagnosed with radiculopathy and experiencing neck pain radiating to one of the upper limbs. Neck and upper limb pain intensity between 3 and 8 based on the Numerical Rating Scale (NRS). At least one month has passed since symptom onset. Presence of an active trigger point in the affected levator scapula muscle (diagnosed by a physiotherapist based on Travell & Simons criteria: (1) palpation of a taut band in the target muscle, (2) identification of a tender spot within the taut band, (3) reproduction of pain similar to the patient's complaint, and (4) painful limitation of the muscle's range of motion. Individuals with at least three of these criteria are considered to have an active trigger point and will be included in the study).
Exclusion criteria:
History of previous neck surgery History of malignancy in the cervical or thoracic region Skin disorders in the neck and shoulder area Fear of needles Lack of cooperation during treatment Presence of cognitive impairment Previous neurological injuries in the upper limb Hyperreflexia Patients diagnosed with myelopathy History of trauma to the neck, thoracic, or shoulder area Use of anticoagulant medications Pregnancy or possibility of pregnancy Presence of rheumatoid conditions Nerve entrapment in the upper limb or brachial plexus Possibility of spinal cyst or tumor Contraindications for electrotherapy Previous physiotherapy treatment for the same condition within the past month
Age
From **18 years** old to **55 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study will be assigned to either the control or intervention group in a 1:1 ratio. To ensure concealment of group assignments, a physiotherapist who is not part of the study will be responsible for randomization. The Random Allocation Software 1.0.0 will be used for this purpose. This software will be instructed to randomly assign 40 patients to intervention and control groups using blocks of 2 and 4. Then, according to the order specified by the randomization software, the letters A and B—representing the intervention and control groups for the therapist—will be written on papers. The individual writing them will not be aware of the group assignments. These papers will then be placed in opaque, numbered envelopes, sealed, and handed over to the intervention therapist. This ensures that the therapist cannot guess the group assignments. During the study, the numbered envelopes will be opened sequentially, determining the group allocation for each incoming patient.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the dry needling technique, it is challenging for the researcher to design the study as double-blind. Therefore, blinding in this study will be single-blind. In this study, the examiner will be blinded to the group assignments, the interventions performed, and the study objectives. To ensure blinding of the examiner regarding the intervention, after the interventions are conducted—whether in the intervention or control group—a matte paper tape will be placed over the targeted trigger point to conceal the needle entry site. This ensures that the examiner remains unaware of whether the dry needling technique has been performed or not.
Placebo
Not used
Assignment
Parallel
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
International Relations Office, No 2 Central Building, Tabriz University of Medical Sciences, University Street, Tabriz,
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Approval date

2025-05-12, 1404/02/22

Ethics committee reference number

IR.TBZMED.REC.1404.165

Health conditions studied

1

Description of health condition studied

Radiculopathy

ICD-10 code

M47.2

ICD-10 code description

Other spondylosis with radiculopathy

Primary outcomes

1

Description

Pain

Timepoint

Base line, at the beginning and end of each session, and again one month after the treatment.

Method of measurement

NRS

Secondary outcomes

1

Description

Cervical Range of Motion

Timepoint

Before starting the treatment and at the end of the tenth session

Method of measurement

Goniometer

2

Description

Neck Disability

Timepoint

Before starting the treatment and after the final session and one month after the last treatment session

Method of measurement

Neck Disability Index Questionnaire

3

Description

Quality of Life

Timepoint

After the final session and one month after the last treatment session

Method of measurement

SF-36 Questionnaire

4

Description

The Exercise Adherence

Timepoint

After the final session and one month after the last treatment session

Method of measurement

The Exercise Adherence Rating Scale Questionnaire

5

Description

Patient Satisfaction

Timepoint

After the final session and one month after the last treatment session

Method of measurement

Patient Satisfaction Questionnaire

Intervention groups

1

Description

Intervention group: Participants in the intervention group will receive dry needling treatment for the levator scapulae muscle in addition to routine physiotherapy.To perform dry needling in this muscle, the therapist first wears latex gloves on both hands. After disinfecting their hands and the target area with 70% ethanol alcohol, the technique is carried out using a sterile Dong Bang needle from South Korea, measuring 0.3×50 mm.The dry needling technique varies depending on the location of the patient's most painful trigger point: For higher sections of the muscle, the patient lies on their side, and the muscle is pinched. The needle is inserted perpendicularly to the skin, aimed toward the therapist's thumb. For lower sections of the muscle, the patient lies prone with their affected arm placed on their lower back. In the region of the superior angle of the scapula, the needle is inserted at an angle close to the skin surface, directed toward the superior angle of the scapula.The intervention uses a Fast in-Fast out technique, with the goal of eliciting or palpating local twitch responses. The needle motion continues until a twitch response is observed or up to ten repetitions if no response is detected.

Category

Rehabilitation

2

Description

Control group: Participants in the control group will receive only routine physiotherapy treatments for cervical radiculopathy. This treatment begins with High-TENS therapy at 120 Hz frequency with a pulse duration of 60 microseconds, combined with a hot pack for 25 minutes. After that, ultrasound therapy is applied for 4 minutes at 1 MHz frequency with an intensity of 1.6 W/cm². Additionally, manual traction is performed for the cervical region. Neurodynamic techniques based on the Shacklock method, including sliders and tensioners, will be applied according to the patient's needs. Throughout

the sessions, routine therapeutic exercises and necessary patient education will be part of the program.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
physiotherapy clinic of Asadabadi hospital

Full name of responsible person
Hakimeh adigozalih

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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
Hakimeh adigozali

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiotherapy

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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