Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison the effects of Cervical Collar and Multimodal Physiotherapy on pain, disability ,range of motion and neck muscles endurance for people with acute Cervical Radiculopathy: a Randomised Controlled Trial

Protocol summary

Study aim

To determine the effects of a cervical collar and multiple physiotherapy interventions on pain, disability, range of motion, and cervical muscle endurance in individuals with acute cervical radiculopathy through a randomized clinical trial.

Design

Three-arm, single-center, parallel-group, randomized controlled clinical trial with a total sample size of 57 participants. Randomization will be using Random Allocation Software.

Settings and conduct

After ethical approval and IRCT registration, patients with cervical radiculopathy will be recruited from Ahvaz medical centers, randomly allocated using a software into 3 groups, and evaluated after a 4-week treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18 and 60 years, Reported neck or arm pain for less than one month, Pain intensity exceeding 4 on the Visual Analog Scale (VAS), Cervical radiculopathy diagnosed by a neurosurgeon. Exclusion criteria: Myelopathy, neurological disorder, tumor, rheumatic disease, Previous surgery in the cervical region.

Intervention groups

Cervical Collar: Use of a semi-rigid cervical collar provided by the researchers, worn continuously for 4 weeks with gradual reduction in the final week. Cervical Collar plus Physiotherapy: Same collar protocol as Group 1 plus multimodal physiotherapy including TENS (120 Hz, 100 µs, 20 min), hot pack (20 min), ultrasound, and progressive strengthening and stretching exercises for 12 sessions over 4 weeks (3 sessions per week). Control: No intervention; participants continue their usual activities without additional therapeutic procedures.

Main outcome variables

Pain intensity (VAS), neck disability (NDI), cervical ROM (by goniometer), and cervical muscle endurance.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251018067674N1**
Registration date: **2025-11-26, 1404/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-11-26, 1404/09/05**
Update count: **0**

Registration date

2025-11-26, 1404/09/05

Registrant information

Name
Behrouz Ghelichi
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

2025-11-22, 1404/09/01

Expected recruitment end date

2025-12-22, 1404/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison the effects of Cervical Collar and Multimodal Physiotherapy on pain, disability ,range of motion and neck muscles endurance for people with acute Cervical Radiculopathy: a Randomised Controlled Trial

Public title
Comparison the effects of Cervical Collar and Multimodal Physiotherapy on pain, disability ,range of motion and neck muscles endurance for people with acute Cervical Radiculopathy: a Randomised Controlled Trial

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 18 and 60 years Reported neck or arm pain for less than one month Pain intensity exceeding 4 on the Visual Analog Scale (VAS) Cervical radiculopathy diagnosed by a neurosurgeon.

Exclusion criteria:
Myelopathy neurological disorder tumor rheumatic disease Previous surgery in the cervical region

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **57**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process is performed using a random sequence generation software (Random Allocation Software). In this method, the three groups have equal sample sizes, and participants are matched based on age and gender. This approach corresponds to a stratified block randomization method.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Deputy of Research and Technology, Jundishapur University of Medical Sciences, Ahvaz

City
Ahzav

Province
Khouzestan

Postal code
61357-33133

Approval date
2025-08-30, 1404/06/08

Ethics committee reference number
IR.AJUMS.REC.1404.273

Health conditions studied

1

Description of health condition studied
Acute cervical radiculopathy

ICD-10 code
M54.12

ICD-10 code description
Radiculopathy, cervical region

Primary outcomes

1

Description
Pain intensity

Timepoint
Before intervention, after completing treatment sessions, one month later.

Method of measurement
Patients' pain intensity will be assessed using the 10-point Visual Analogue Scale (VAS). In this scale, a score of 0 indicates no pain, while a score of 10 represents the most severe pain imaginable. Participants will be asked to mark the level of pain they experience during activity on a line graded from 0 to 10.

2

Description
neck disability

Timepoint
Before intervention, after completing treatment sessions, one month later.

Method of measurement
Using the Neck Disability Index (NDI) questionnaire: This questionnaire, translated into Persian and validated by Mousavi et al. (2007), evaluates the impact of neck pain on daily life and social activities. It assesses how neck pain interferes with activities such as reading, concentration, personal care, driving, sleeping, and lifting objects. The presence and severity of headaches are also assessed. Each item is rated on a 6-point scale (0–5), where a score of 0 indicates no disability and 50

represents complete disability or maximum functional limitation.

Secondary outcomes

1

Description
cervical range of motion
Timepoint
Before intervention, after completing treatment sessions, one month later.
Method of measurement
In this test, the range of cervical motion, including flexion, extension, rotation, and lateral flexion, is assessed. The participant sits at the edge of a table and is asked to bend the head forward and backward, as well as to rotate and laterally flex the neck. The movements are measured and recorded using a cervical goniometer in degrees.

2

Description
cervical muscle endurance
Timepoint
Before intervention, after completing treatment sessions, one month later.
Method of measurement
In this test, the endurance of the cervical flexor muscles is evaluated. The participant lies in a supine position with knees bent and is asked to tuck the chin and flex the neck, lifting the head and neck approximately 2.5 cm above the table. The duration for which the participant can maintain this position is recorded in seconds using a stopwatch. Surface electromyography studies have shown that in this position, the activity of the longus colli and longus capitis muscles increases progressively, while the sternocleidomastoid and scalene muscles maintain constant activity. Therefore, this clinical test primarily emphasizes the endurance of the deep cervical flexors.

Intervention groups

1

Description
Intervention group 1: The cervical collar used in this study will be a semi-rigid type, available in four standard sizes, and should fit the patient’s neck comfortably and appropriately. The collars will be provided free of charge by the researchers. Patients will be instructed to wear the collar continuously for four weeks, day and night, as much as tolerated. During the final week, they will be advised to gradually reduce collar use, and by the end of the fourth week, to discontinue it completely. Participants will be asked to record the date they began using the collar.
Category
Rehabilitation

2

Description
Intervention group 2: Physiotherapy, emphasizing a standardized multimodal rehabilitation approach, includes TENS, hot pack therapy, ultrasound, and strengthening and stretching exercises.TENS is a commonly used analgesic modality for pain control. A 2007 meta-analysis identified TENS as an effective method for reducing musculoskeletal pain. In patients with neck pain, pain reduction following TENS has been reported compared to control groups, particularly among those with milder symptoms. However, the effect of TENS is greater when combined with exercise therapy than when used alone.Exercise therapy during the acute phase of cervical radicular pain has shown beneficial effects in pain reduction compared to control groups, though no significant improvement in functional outcomes was observed.Treatment sessions will be conducted three times per week for four weeks (a total of 12 sessions). Conventional TENS will be administered at a frequency of 120 Hz and pulse duration of 100 microseconds for 20 minutes, while a hot pack will be applied to the affected area for 20 minutes.During weeks 1 and 2, patients will perform pain-relieving and foraminal-opening positions. In week 3, deep cervical flexor strengthening exercises will be introduced, with gradual increases in intensity and repetitions over sessions. In week 4, stretching exercises will be added to the strengthening program.
Category
Rehabilitation

3

Description
Control group: Participants in this group will not receive any intervention and will continue their usual daily activities without additional therapeutic procedures.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Musculoskeletal Rehabilitation Research Center
Full name of responsible person
Shahin Goharpey
Street address
Ahvaz, Jundishapour University of Medical Sciences Campus, Opposite the M.R.I. Building, Rehabilitation School, Musculoskeletal Rehabilitation Research Center
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goharpay-sh@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Abdollah Rafiei

Street address

Vice Chancellor for Research and Technology,Ahvaz Jondishapur University of Medical Sciences, golestan street, Ahvaz,Iran.

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Grant name

Ahvaz Jondishapur University of Medical Sciences

Grant code / Reference number

PHT-0404

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Behrouz Ghelichi

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Physical therapy Department, Rehabilitation School, opposite the MRI Building, Jundishapour University of Medical Sciences, Ahvaz

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Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Position

PhD student

Latest degree

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Other areas of specialty/work

Physiotherapy

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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
The person's information will be confidential and the results will be as collective statistics
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
This clinical trial will be an research article and its protocol, results report and statistical analysis will be published to be used by therapists.
When the data will become available and for how long
If the journal has requested access to the data at any time, the data will be provided.
To whom data/document is available
Journal editors and Reviewers
Under which criteria data/document could be used
Sometimes for re-analysis or for use in meta-analysis studies.
From where data/document is obtainable
Project manager
What processes are involved for a request to access data/document
It should be send email to project manager and after reviewing the reason for requesting the data, they will be send.
Comments