

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of Phonophoresis With And Without Muscle Energy Technique On Pain, Cervical Range of Motion And Functional Disability In Patients With Degenerative Cervical Radiculopathy: A Randomized Controlled Trial

Protocol summary

Study aim

To determine the therapeutic effects of phonophoresis with and without muscle energy technique on pain, functional disability, and range of motion among patients with degenerative cervical radiculopathy.

Design

parallel-group, double-blinded, randomized control trial

Settings and conduct

The outdoor patient department of the physical therapy department in the hospital. Both assessor of outcomes (fellow physiotherapist) and statistician (data analyzer) will be blinded. They both will have no knowledge of the patient's group and treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Ages between 30 and 65 years 2. CR diagnosis with sub-acute history and physical examination findings. 3. Diagnosed CR patients referred from a physician. 4. Patients were diagnosed based on the prediction rule. i.e. (a) unilateral upper limb sensory and motor function dysfunction was observed (including muscle weakness, paresthesia, and sharp pain. (b) when positive results were found in three of these four tests (Spurling's test, The ipsilateral cervical spinal rotation less than 60 degrees, Distraction test, Upper Limb Neurodynamic Test 1). 5. Both male and female
Exclusion criteria: 1. Diabetes mellitus 2. Peripheral and central nervous system disease 3. Polyneuropathy 4. Malignancy 5. History of surgical intervention on the neck area 6. Certain surgical indications (e.g., progressive neurological deficit). 7. "Red flags" (e.g. tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged steroid use) 8. Cervical spine injections (steroidal) in the past 2 weeks 9. Current use of steroidal medication prescribed for radiculopathy symptoms 10. bilateral upper limb sensory or motor complaints

Intervention groups

the intervention group will receive the ketoprofen

phonophoresis intervention along with muscle energy technique intervention.

Main outcome variables

1-pain 2- Range of motions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211130053231N1**

Registration date: **2022-08-18, 1401/05/27**

Registration timing: **retrospective**

Last update: **2022-08-18, 1401/05/27**

Update count: **0**

Registration date

2022-08-18, 1401/05/27

Registrant information

Name

Maheen Ashraf

Name of organization / entity

University of Lahore

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-05, 1399/12/15

Expected recruitment end date

2021-04-05, 1400/01/16

Actual recruitment start date

2021-07-01, 1400/04/10

Actual recruitment end date

2021-09-18, 1400/06/27

Trial completion date

2021-10-18, 1400/07/26

Scientific title

Effects of Phonophoresis With And Without Muscle Energy Technique On Pain, Cervical Range of Motion And Functional Disability In Patients With Degenerative Cervical Radiculopathy: A Randomized Controlled Trial

Public title

Effect of Muscle energy technique in treatment of cervical radiculopathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

CR diagnosis with sub-acute history and physical examination findings Diagnosed CR patients referred from a physician. Patients were diagnosed based on the prediction rule. i.e. (a) unilateral upper limb sensory and motor function dysfunction was observed (including muscle weakness, paresthesia, and sharp pain. (b) when positive results were found in three of these four tests (Spurling's test, The ipsilateral cervical spinal rotation less than 60 degrees, Distraction test, Upper Limb Neurodynamic Test 1) age between 30 to 65 both male and female

Exclusion criteria:

Diabetes mellitus Peripheral and central nervous system disease Polyneuropathy Malignancy History of surgical intervention on the neck area Certain surgical indications (e.g., progressive neurological deficit) "Red flags" (e.g. tumor, fracture, rheumatoid arthritis, osteoporosis, prolonged steroid use) Cervical spine injections (steroidal) in the past 2 week Current use of steroidal medication prescribed for radiculopathy symptoms Bilateral upper limb sensory and motor dysfunction

Age

From **30 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: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

lottery-based randomization procedure: All the recruited subjects' names and ids were written on individual small paper/chits. All these papers were folded and put into a box. The box was shaken to mix all the papers. Then one by one each slip was drawn from the box. The group of

the first drawn slip patient was sorted into group A and later with each draw of the paper all subjects were placed alternatively in the group B and group A

Blinding (investigator's opinion)

Double blinded

Blinding description

both assessor of outcomes (fellow physiotherapist) and statistician (data analyzer) will be blinded. They both will have no knowledge of the patient's group and treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

University of Lahore

Street address

1-Km Defense Road, near Bhuptian Chowk

City

Lahore

Postal code

54000

Approval date

2021-07-15, 1400/04/24

Ethics committee reference number

IRB-UOL-FAHS/907/2021

Health conditions studied**1****Description of health condition studied**

Degenerative cervical radiculopathy

ICD-10 code

M50.10

ICD-10 code description

Cervical disc disorder with radiculopathy, unspecified cervical region

Primary outcomes**1****Description**

pain

Timepoint

Before intervention, after 2 weeks and after 4 weeks of intervention

Method of measurement

Visual analogue scale

2

Description

cervical range of motion

Timepoint

Before intervention, after 2 weeks and after 4 weeks of intervention

Method of measurement

goniometer

Secondary outcomes

1

Description

Functional disability

Timepoint

Before intervention, after 2 weeks and after 4 weeks of intervention

Method of measurement

Neck disability index (NDI)

Intervention groups

1

Description

Intervention group: Group A (n=25) was treated with ketoprofen gel phonophoresis along with post isometric relaxation technique of muscle energy technique 3 times/week on alternate days (total 12 sessions) for 4 weeks. Conservative physical therapy treatment was also delivered which included cervical traction, Active range of motions, and thermotherapy. For phonophoresis, Fastum gel (2.5% w/w ketoprofen gel) was mixed with aqua sonic gel as a coupling medium. The US machine was adjusted in continuous mode at 1 MHz frequency while an intensity of 1.5W/cm² will be applied for 10 mins on a circular basis. For MET each patient received 4 repetitions of post-isometric relaxation. each contraction required 20% of submaximal effort and was sustained for 8 secs. Then the muscle to be stretched for 20 seconds, which was followed by a rest period of 5 seconds.

Category

Rehabilitation

2

Description

Control group: Group B (n =25) received ketoprofen phonophoresis only 3 times/week on alternate days (total 12 sessions) for 4 weeks. Conservative physical therapy treatment was also delivered which included cervical traction, Active range of motions, and thermotherapy. For phonophoresis, Fastum gel (2.5% w/w ketoprofen gel) was mixed with aqua sonic gel as a coupling medium. The US machine was adjusted in continuous mode at 1 MHz frequency while an intensity of 1.5W/cm² will be applied for 10 mins on a circular basis.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Allied Hospital Faisalabad

Full name of responsible person

Dr. Sobia Nawaz

Street address

adjacent Faisalabad Medical University , Near Sargodha Road on dr. Tusi road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Prof. Dr. Ashfaq Ahmed

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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

University of Lahore

Proportion provided by this source

100

Public or private sector

Private

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

University of Lahore

Full name of responsible person

Maheen Ashraf

Position

Student

Latest degree

Bachelor

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