Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

Phone
+92 41 8546761

Email address
msptn02191027@student.uol.edu.pk

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/cm_2 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/cm_2 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
City
Faisalabad
Postal code
38000
Phone
+92 336 3877833
Email
info@pmc.edu.pk

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University of Lahore
Full name of responsible person
Prof. Dr. Ashfaq Ahmed
Street address
1-Km Defense Road, near Bhuptian Chowk
City
Lahore
Postal code
54000
Phone
+92 42 111 865 865
Email
info@uol.edu.pk
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
Street address
Shadman town house p82 Faisalabad
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 334 0071665
Fax
Email
msptn02191027@student.uol.edu.pk

Person responsible for scientific 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
Street address
Shadman town house p82 Faisalabad
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 334 0071665
Fax
Email
msptn02191027@student.uol.edu.pk

Person responsible for updating data

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
Street address
Shadman town house p82 Faisalabad
City
Faisalabad
Province
Punjab
Postal code
38000
Phone
+92 334 0071665
Fax
Email
msptn02191027@student.uol.edu.pk

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