Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

EFFECTS OF PHONOPHORESIS WITH AND WITHOUT DICLOFENAC DIETHYLAMINE WITH ROUTINE PHYSICAL THERAPY ON PAIN AND RANGE OF MOTION IN PATIENTS WITH CERVICAL SPONDYLOSIS

Protocol summary

Study aim

The main aim of the study is to compare the effects of phonophoresis with and without diclofenac diethylamine phonophoresis with routine physical therapy in patients who are diagnosed with cervical spondylosis.

Design

It will be single blinded study, in which the accessor will be unaware of the treatment group.

Settings and conduct

The data will be collected from the University of Lahore Teaching Hospital. The study population will be consisted of patients with cervical spondylosis.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: • Patients with cervical spondylosis. • Aged from 30 to 60 years of patient with cervical spondylosis. • Pre-diagnosed cases of cervical spondylosis. • Both the genders. • Patients referred by orthopedic surgeons. • Patients who are willing to participate in this study. • Patients who are diagnosed with cervical spondylosis by other professionals/doctors. Exclusion Criteria: • Patients with cervical fracture. • Patients with vertebrobasilar insufficiency. • Presence of other significant rheumatic disease variants. • Patients who have history of any cervical spine surgery. • Patients who have active infection. • Pregnant Females. • Ankylosing Spondylitis.

Intervention groups

Intervention Group A: Diclofenac diethylamine phonophoresis will be done on the participants along with routine physical therapy to check the effectiveness of diclofenac diethylamine phonophoresis and how it influence the range of motion, pain and quality of life. Group B: Phonophoresis with only aqua gel and routine physical therapy will be provided to the patients.

Main outcome variables

Visual Analogue Scale and Neck Disability Index for Pain and Cervical Disability respectively and Universal goniometer will be used for Range of motion and Short Form -36 for Quality of Life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240713062426N1**
Registration date: **2024-07-25, 1403/05/04**
Registration timing: **registered_while_recruiting**

Last update: **2024-07-25, 1403/05/04**
Update count: **0**

Registration date

2024-07-25, 1403/05/04

Registrant information

Name

Sara Khatoon

Name of organization / entity

The University of Lahore

Country

Pakistan

Phone

+92 333 4104427

Email address

sarakhatoon4.sk@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-01, 1402/11/12

Expected recruitment end date

2024-08-19, 1403/05/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
EFFECTS OF PHONOPHORESIS WITH AND WITHOUT DICLOFENAC DIETHYLAMINE WITH ROUTINE PHYSICAL THERAPY ON PAIN AND RANGE OF MOTION IN PATIENTS WITH CERVICAL SPONDYLOSIS

Public title
Effects of Phonophoresis with Diclofenac Diethylamine on cervical spondylosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients of both genders of age range from 30-60 years Pre-diagnosed cases of cervical spondylosis with and without radiculopathy Patients referred by orthopedic surgeons. Patients who are diagnosed with cervical spondylosis by other professionals/doctors.
Exclusion criteria:
Patients with cervical fracture. Patients with vertebrobasilar insufficiency Presence of other significant rheumatic disease variants. Patients who have history of any cervical spine surgery. Patients who have active infection. Pregnant Females Ankylosing Spondylitis
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization will be used by one of the research team members who will be blinded and not involve in patient recruitment or assessment or data analysis. Participants are randomly allocated into two groups through drawing a number.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study is a single blinded study in which outcome assessor will be unaware of the treatment group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee Faculty of Allied Health Sciences The University of Lahore
Street address
1-Km Defence Road، near Bhuptian Chowk، Lahore, Punjab
City
Lahore
Postal code
54000
Approval date
2023-12-12, 1402/09/21
Ethics committee reference number
REC-UOL-654-01-2024

Health conditions studied

1

Description of health condition studied
Cervical Spondylosis
ICD-10 code
M47.812
ICD-10 code description
Spondylosis without myelopathy or radiculopathy, cervical region

Primary outcomes

1

Description
Functional Disability
Timepoint
Before intervention and at the 2nd and 4th weeks after intervention
Method of measurement
Neck Disability Index

2

Description
Pain
Timepoint
Before intervention and at 2nd and 4th weeks after intervention
Method of measurement
Visual Analogue Scale

3

Description
Quality of Life
Timepoint
Before intervention and at 2nd and 4th weeks after intervention
Method of measurement

36-Item Short Form Survey (SF-36)

4

Description
Range of Motion
Timepoint
Before intervention and at 2nd and 4th weeks after intervention
Method of measurement
Goniometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:
Category
Treatment - Devices

2

Description
Control group:
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
The University of Lahore Teaching Hospital
Full name of responsible person
Dr. Asim Arif
Street address
1-Km Defence Road، near Bhuptian Chowk، Lahore, Punjab
City
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Postal code
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+92 335 1450137
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The University of Lahore
Full name of responsible person
Sara Khatoon
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Grant name
None
Grant code / Reference number
N/A
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
None
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
The University of Lahore
Full name of responsible person
Sara Khatoon
Position
Student
Latest degree
Master
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)
Yes - There is a plan to make this available

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
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Yes - There is 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

Title and more details about the data/document
Demographic data and data related to final outcome will be shared by maintaining the confidentially.

When the data will become available and for how long
Data will be available after the publication of findings till six moths

To whom data/document is available
Sara Khatoon

Under which criteria data/document could be used
For research purpose

From where data/document is obtainable
To the corresponding author of the study, Sara Khatoon and can contact on +923334104427, sarakhatoon4.sk@gmail.com

What processes are involved for a request to access data/document
Open access and there is the traditional public data release where anyone can get access to the data.

Comments