

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 assessor 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

The University of Lahore

Full name of responsible person

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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 scientific inquiries

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Bachelor

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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 confidentiality.

When the data will become available and for how long

Data will be available after the publication of findings till six months

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