

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparative effects of curcumin and naproxen gels with ultrasound-enhanced delivery for cervical myofascial pain treatment

Protocol summary

Study aim

The aim of the study is to evaluate and compare the effectiveness of curcumin gel and naproxen gel in the treatment of cervical myofascial pain syndrome (CMPS).

Design

Pragmatic, community based, parallel group, double blinded, randomized controlled trial. Total 105 patients will be enrolled. Patients who met our inclusion criteria will be randomized into two groups.

Settings and conduct

Muhammad Rehabilitation Centre, Multan

Participants/Inclusion and exclusion criteria

Inclusion Criteria: All ages diagnosed with cervical myofascial pain syndrome Moderate to severe pain, No contraindications to curcumin or naproxen. Exclusion Criteria: Pregnancy, lactation, severe cervical spine pathology, history of drug allergy, and prior treatment with corticosteroids or other anti-inflammatory medications within four weeks.

Intervention groups

Intervention Protocol: Group A: The respective gel (curcumin) will be applied topically over the affected area at a dose of 2 grams., A therapeutic ultrasound device operating at 1 MHz frequency and 1.5 W/cm² intensity was used. Ultrasound will be applied for 10 minutes in a circular motion over the gel to enhance transdermal drug delivery. Treatments will be administered once daily for four weeks. Group B: The respective gel (naproxen) will be applied topically over the affected area at a dose of 2 grams., A therapeutic ultrasound device operating at 1 MHz frequency and 1.5 W/cm² intensity was used. Ultrasound will be applied for 10 minutes in a circular motion over the gel to enhance transdermal drug delivery. Treatments will be administered once daily for four weeks.

Main outcome variables

Pain (NPRS), Cervical ROM (goniometry), Muscle tenderness (Pressure pain threshold scale), Quality of life (SF-36), Functional Status (McGill Questionnaire), ESR,

CRP, IL-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230202057310N13**

Registration date: **2024-12-22, 1403/10/02**

Registration timing: **prospective**

Last update: **2024-12-22, 1403/10/02**

Update count: **0**

Registration date

2024-12-22, 1403/10/02

Registrant information

Name

Imran Ahmad Khan

Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

Country

Pakistan

Phone

+92 333 6120602

Email address

imran.ahmad@mnsuam.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-04, 1403/10/15

Expected recruitment end date

2025-04-04, 1404/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparative effects of curcumin and naproxen gels with ultrasound-enhanced delivery for cervical myofascial pain treatment

Public title
Curcumin and naproxen gels with ultrasound-enhanced delivery for cervical myofascial pain treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Individuals of all ages diagnosed with cervical myofascial pain syndrome Moderate to severe pain No contraindications to curcumin or naproxen.

Exclusion criteria:
Pregnancy , Lactation Severe cervical spine pathology, History of drug allergy, and prior treatment with corticosteroids or other anti-inflammatory medications within four weeks.

Age
No age limit

Gender
Both

Phase
1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
This randomization will be done by computer-generated numbers to ensure fairness. Medications will be given in numbered white boxes, each with a unique medication number. The treatment codes will be kept by the principal investigator.

Blinding (investigator's opinion)
Double blinded

Blinding description
Statistical analyser and outcome assessor will be kept blind so that the result obtained will be without biasness.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences

Street address

Multan

City

MULTAN

Postal code

66000

Approval date

2024-12-04, 1403/09/14

Ethics committee reference number

MIMAS/20/12/IAK

Health conditions studied

1

Description of health condition studied

Cervical myofascial pain syndrome

ICD-10 code

M60

ICD-10 code description

Myositis

Primary outcomes

1

Description

Pain

Timepoint

4 weeks

Method of measurement

NPRS

2

Description

Cervical ROM

Timepoint

4 WEEKS

Method of measurement

Goniometry

3

Description

Muscle tenderness

Timepoint

4 weeks

Method of measurement

Pressure pain threshold scale

Secondary outcomes

1

Description

Serological findings
Timepoint
4 weeks
Method of measurement
ESR, CRP,IL-6

2

Description
Quality of life
Timepoint
4 weeks
Method of measurement
SF-36 scale

3

Description
Functional Status
Timepoint
4 weeks
Method of measurement
McGill Questionnaire

Intervention groups

1

Description
Intervention group: Group A: The respective gel (curcumin) will be applied topically over the affected area at a dose of 2 grams., A therapeutic ultrasound device operating at 1 MHz frequency and 1.5 W/cm² intensity was used.Ultrasound will be applied for 10 minutes in a circular motion over the gel to enhance transdermal drug delivery.Treatments will be administered once daily for four weeks.

Category
Treatment - Drugs

2

Description
Intervention group: Group B: The respective gel (naproxen) will be applied topically over the affected area at a dose of 2 grams., A therapeutic ultrasound device operating at 1 MHz frequency and 1.5 W/cm² intensity was used.Ultrasound will be applied for 10 minutes in a circular motion over the gel to enhance transdermal drug delivery.Treatments will be administered once daily for four weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Muhammad Rehabilitation Centre, Multan
Full name of responsible person

Komal Ammar Bukhari
Street address
Bosan Road
City
Multan
Postal code
66000
Phone
+92 312 6827130
Email
komalbukhari608@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Muhammad Institute of Medical and Allied Sciences,
Multan, Pakistan
Full name of responsible person
Qurat-UI-Ain
Street address
Multan
City
MULTAN
Postal code
66000
Phone
+92 312 6827130
Email
qain0635@gmail.com
Grant name
Student fund
Grant code / Reference number
MIMAS/04/25/Mawra
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Muhammad Institute of Medical and Allied Sciences,
Multan, Pakistan
Proportion provided by this source
70
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
Muhammad Institute of Medical and Allied Sciences,
Multan, Pakistan.
Full name of responsible person
Maliha Khalid Khan

Position

Lecturer

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

Street address

Multan

City

MULTAN

Province

Punjab

Postal code

66000

Phone

+92 312 6827130

Email

malihatareen1997@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Muhammad Nawaz Sharif University of Agriculture
Multan

Full name of responsible person

Imran Ahmad Khan

Position

Coordinator Department of Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Old shuja Abad road Multan

City

Multan

Province

Punjab

Postal code

66000

Phone

+92 333 6120602

Email

imran.ahmad@mnsuam.edu.pk

Person responsible for updating data**Contact****Name of organization / entity**

Muhammad Institute of Medical and Allied Sciences,
Multan, Pakistan

Full name of responsible person

Mawra Majeed

Position

Punjab

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

Street address

Multan

City

MULTAN

Province

Punjab

Postal code

66000

Phone

+92 312 6827130

Email

mawra1023@gmail.com

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