Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Email address

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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

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66000

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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-Ul-Ain

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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
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Physiotherapy
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Person responsible for scientific inquiries

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Name of organization / entity
Muhammad Nawaz Sharif University of Agriculture Multan
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Person responsible for updating data

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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