

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Formulation and Comparative Efficacy of Ashwagandha, Sesame, and Rosemary Gel Vs Diclofenac Gel with Ultrasound in Back Myofascial Pain

Protocol summary

Study aim

This study aims to ascertain if the combination of herbal medicine (Ashwagandha, sesame, and rosemary) and therapeutic (Ultrasound therapy) interventions provides a comparative effect, alleviating and managing back pain, improving muscle function, promoting recovery and improving overall mobility in patients with MPS and to compare the effectiveness of Ashwagandha, sesame, and rosemary oils versus Diclofenac gel, both combined with therapeutic ultrasound, in managing back myofascial pain.

Design

Pragmatic, community based, parallel group, double blinded, randomized controlled trial. Total 110 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: • Chronic or subacute myofascial back pain persisting for at least 4 weeks. • Pain score ≥ 4 on the Numerical Pain Rating Scale (NPRS). • Willingness to undergo ultrasound therapy and use the prescribed gel. Exclusion Criteria: • Dermatological issues or open wounds on the back. • Known allergies to any components of the gels. • Use of systemic corticosteroids or analgesics. • Severe musculoskeletal conditions or neurological disorders.

Intervention groups

Group 1: ASR Gel Group: The ASR gel will be applied to the affected area, followed by 10 minutes of ultrasound therapy using a 1 MHz ultrasound device set to 1 W/cm² in continuous mode. Group 2: Diclofenac Gel Group: Diclofenac gel will be applied in a similar manner, followed by identical ultrasound therapy parameters. Both groups received treatment 3 times per week for 6 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: **IRCT20230202057310N12**

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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+92 333 6120602

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-07, 1403/10/18

Expected recruitment end date

2025-03-30, 1404/01/10

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Formulation and Comparative Efficacy of Ashwagandha, Sesame, and Rosemary Gel Vs Diclofenac Gel with Ultrasound in Back Myofascial Pain

Public title
Ashwagandha, Sesame, and Rosemary Gel Vs Diclofenac Gel with Ultrasound in Back Myofascial Pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic or subacute myofascial back pain persisting for at least 4 weeks Pain score ≥ 4 on Numerical Pain rating scale (NPRS) Willingness to undergo ultrasound therapy and use the prescribed gel.

Exclusion criteria:

Dermatological issues or open wounds on the back Known allergies to any components of the gels Use of systemic corticosteroids or analgesicS Severe musculoskeletal conditions or neurological disorders

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
1

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **110**

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

Bosan Road

City

Multan

Postal code

66000

Approval date

2024-11-25, 1403/09/05

Ethics committee reference number

MIMAS/9/02/IAK

Health conditions studied

1

Description of health condition studied

Back 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

Lumber 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 1: The ASR gel was applied to the affected area, followed by 10 minutes of ultrasound therapy using a 1 MHz ultrasound device set to 1 W/cm² in continuous mode. 3 times per week for 4 weeks.

Category

Treatment - Drugs

2

Description

Intervention group: Group 2: Diclofenac gel was applied in a similar manner, followed by identical ultrasound therapy parameters. 3 times per week for 4 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

Multan

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MULTAN

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66000

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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 Ul Ain

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Bosan Road

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Email

qain0635@gmail.com

Grant name

Student fund

Grant code / Reference number

MIMAS/15/12/Aqsa

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

Punjab

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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

Contact

Name of organization / entity
Muhammad Institute of Medical and Allied Sciences,

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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