Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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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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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+92 333 6120602
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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
Street address
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Postal code
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Phone
+92 312 6827130
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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Latest degree
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Medical Pharmacy

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Person responsible for updating data

Contact

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

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Position
Last year student of DPT

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Physiotherapy

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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