

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 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  $\geq 4$  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/cm<sup>2</sup> 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

##### Phone

+92 333 6120602

##### Email address

imran.ahmad@mnsuam.edu.pk

##### 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  $\geq 4$  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/cm<sup>2</sup> 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

##### City

MULTAN

##### Postal code

66000

#### Phone

+92 333 6120602

#### 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

##### Street address

Bosan Road

##### City

Multan

##### Postal code

66000

##### 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

#### Street address

Multan  
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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**  
Punjab  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Medical Pharmacy  
**Street address**  
Old shuja Abad road Multan  
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**Province**  
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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**  
Aqsa Sajjad  
**Position**  
Last year student of DPT  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Physiotherapy  
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MULTAN  
**Province**  
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66000  
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+92 318 1477078  
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aqsasajjad1272@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