

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Formulation and evaluation of Jasminum sambac gel for musculoskeletal injuries with and without phonophoresis

#### Protocol summary

##### Study aim

The aim of our study is to evaluate the anti-nociceptive and anti-inflammatory effects of J. sambac gel with superficial massage and phonophoresis.

##### Design

A pragmatic, community-based study. A double-blinded, randomized controlled trial with a parallel group design of 200 patients, will enroll between February 2023 to April 2023.

##### Settings and conduct

The study will be conducted at Muhammad Physiotherapy and Rehabilitation Center, Multan, Pakistan. After approval obtained from the institutional ethical committee.

##### Participants/Inclusion and exclusion criteria

Patients with 1st and 2nd grade muscular and soft tissue injuries will be included in this study. Both genders, aged 16-70 years. While patients have any type of allergy from the ingredients used in the formulation or other skin problems, cancer, diabetic peripheral neuropathy, other neurological disorder, any type of bone fractures or open injuries, patient with casts or splints will be excluded from this study.

##### Intervention groups

Participants will be equally distributed into four parallel groups. The first and second groups will receive topical application of J. sambac and diclofenac diethyl-ammonium 1% gel respectively through phonophoresis with therapeutic ultrasound, while the third and fourth groups will receive topical application of J. sambac gel and diclofenac diethyl-ammonium 1% gel respectively through superficial massage on effected areas of participants.

##### Main outcome variables

Pain, stiffness, activities of daily living, and inflammation

#### General information

##### Reason for update

Only the Position of the Person responsible for general inquiries is changed.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230202057310N1**

Registration date: **2023-03-23, 1402/01/03**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-12-14, 1402/09/23**

Update count: **1**

##### Registration date

2023-03-23, 1402/01/03

##### 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

2023-02-05, 1401/11/16

##### Expected recruitment end date

2023-04-05, 1402/01/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Formulation and evaluation of Jasminum sambac gel for musculoskeletal injuries with and without phonophoresis

## Public title

Analgesic and anti-inflammatory effect of Jasminum sambac gel for musculoskeletal injuries with and without phonophoresis

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

1st and 2nd grade soft tissue injuries 16-70 years Both gender

### Exclusion criteria:

Any type of allergy from the ingredients used in our formulation Skin problem Cancer Diabetic peripheral neuropathy Other neurological disorders Any type of bone fractures Patients with casts Open injuries Patients with splints Patients with casts Patients with splints Open injuries

## Age

From **16 years** old to **70 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Investigator
- Data analyser

## Sample size

Target sample size: **200**

More than 1 sample in each individual

Number of samples in each individual: **50**

Participants will be equally distributed in four groups. 50 participants in each group.

## Randomization (investigator's opinion)

Randomized

## Randomization description

The lottery method will be used for the randomization of participants into four groups in which the names of participants will write on slips and put their name slips in the box, then will be selected independently by the lottery method.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

It is a double blinded study. Both the investigator and the data analyser will be kept blind in order to avoid any biasness. To overcome the biasness of procedure the investigator will be kept blind and for the correct authentication and validation of the results data analyser will be kept blind.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic's Committee of Muhammad Nawaz Shareef University of Agriculture, Multan.

##### Street address

Agriculture Complex, Old Shuja Abad Rd,

##### City

Multan

##### Postal code

66000

#### Approval date

2023-01-21, 1401/11/01

#### Ethics committee reference number

2023/IRB/21/PT/01

## Health conditions studied

### 1

#### Description of health condition studied

Muscular injuries

#### ICD-10 code

M79.1

#### ICD-10 code description

Myalgia

### 2

#### Description of health condition studied

Soft tissue injuries

#### ICD-10 code

M79.9

#### ICD-10 code description

Soft tissue disorder, unspecified

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

Pre and Post evaluation

#### Method of measurement

Numeric Pain Rating Scale

## Secondary outcomes

### 1

#### Description

Activities of Daily Living

#### Timepoint

Pre and Post evaluation

## Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scale

## Intervention groups

### 1

#### Description

Intervention group 1: The first group will receive topical application of gel formulated from aqueous-methanolic (30:70) extract *Jasminum sambac* (10%) through phonophoresis with therapeutic ultrasound (continuous mode, 1 MH, 0.8W/cm<sup>2</sup>), on the affected areas of participants. The gel will be used once and the data will be collected through Numeric pain rating scale (NPRS) and The Western Ontario and McMaster Universities Arthritis Index (WOMAC) scale.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2: The second group will receive topical application of polyherbal gel, formulated from aqueous-methanolic (30:70) extract *Jasminum sambac* (10%), through superficial massage on effected areas of participants. The gel will be used once and the data will be collected through NPRS and WOMAC scales.

#### Category

Treatment - Drugs

### 3

#### Description

Control group 1: The third group will receive diclofenac diethyl-ammonium 1% gel through phonophoresis with therapeutic ultrasound (continuous mode, 1 MH, 0.8W/cm<sup>2</sup>) on affected areas of participants. The gel will be used once and the data will be collected through NPRS and WOMAC scales.

#### Category

Treatment - Drugs

### 4

#### Description

Control group 2: The fourth group will receive diclofenac diethyl-ammonium 1% gel through superficial massage on the affected areas of participants. The gel will be used once and the data will be collected through NPRS and WOMAC scales.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Muhammad Physiotherapy and Rehabilitation Center,  
Multan

#### Full name of responsible person

Qurat-UI-Ain

#### Street address

HBL street near Sabzazar metro station

#### City

Multan

#### Postal code

66000

#### Phone

+92 303 9427506

#### Email

qain0635@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Muhammad Nawaz Sharif University of Agriculture

##### Full name of responsible person

Imran Ahmad Khan

##### Street address

Agriculture Complex, Old Shuja Abad Rd,

##### City

Multan

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66000

##### Phone

+92 333 6120602

##### Email

imranahmadkhandurrani@gmail.com

#### Grant name

Student fund

#### Grant code / Reference number

567890

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Muhammad Nawaz Sharif University of Agriculture

#### Proportion provided by this source

100

#### Public or private sector

Public

#### 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 Nawaz Sharif University of Agriculture

##### Full name of responsible person

Imran Ahmad Khan

**Position**

Coordinator Department of Pharmacy

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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

Muhammad Nawaz Sharif University of Agriculture

**Full name of responsible person**

Dr. Muhammad Asif Raza

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Parasitology

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asif.raza@mnsuam.edu.pk

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

Muhammad Nawaz Sharif University of Agriculture

**Full name of responsible person**

Qurat-Ul-Ain

**Position**

Lecturer

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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