

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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/cm²), 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/cm²) 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

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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

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

Muhammad Nawaz Sharif University of Agriculture

Full name of responsible person

Qurat-UI-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