Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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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-Ul-Ain
Street address
HBL street near Sabzazar metro station
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Muhammad Nawaz Sharif University of Agriculture
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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 updating data

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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