

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Formulation and evaluation of analgesic and anti-inflammatory effect of *Mangifera indica* gel for musculoskeletal injuries with and without phonophoresis

Protocol summary

Study aim

The aim of our study is to evaluate that gel of *M. indica* exerts more significant anti-nociceptive and anti-inflammatory activities with superficial massage or phonophoresis when compared with the diclofenac diethyl ammonium 1% gel with superficial massage or phonophoresis. These activities may be due to the presence of active constituents different phytochemical constituents present in *M. indica* like mangiferin, quercetin and isoquercetin.

Design

A pragmatic, community-based study. A single-blinded, randomized controlled trial with a parallel group design of 200 patients, will enroll between January 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 *M. indica* 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 *M. indica* and diclofenac diethyl-ammonium 1% gel respectively through phonophoresis with therapeutic ultrasound, while the third and fourth groups will receive topical application of *M. indica* 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 updating data was changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220615055179N2**

Registration date: **2023-01-21, 1401/11/01**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-23, 1402/10/02**

Update count: **2**

Registration date

2023-01-21, 1401/11/01

Registrant information

Name

Qurat-UI- Ain

Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

Country

Pakistan

Phone

+92 303 9427506

Email address

quratulain@mimas.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-21, 1401/11/01
Expected recruitment end date
2023-04-21, 1402/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Formulation and evaluation of analgesic and anti-inflammatory effect of Mangifera indica gel for musculoskeletal injuries with and without phonophoresis

Public title
Analgesic and anti-inflammatory effect of Mangifera indica 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

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

Gender
Both

Phase
2-3

Groups that have been masked

- Participant

Sample size
Target sample size: **200**
More than 1 sample in each individual
Number of samples in each individual: **50**
Participants will 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)
Single blinded

Blinding description
The participants will be blinded

Placebo
Not used

Assignment
Parallel

Other design features
NPRS and WOMAC scales will be used for evaluation of anti-nociceptive and anti-inflammatory activities in muscular and soft tissue injuries

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences, Multan.

Street address

HBL street near Sabzazar metro station

City

Multan

Postal code

66000

Approval date

2022-11-21, 1401/08/30

Ethics committee reference number

2022/IRB/2/PT/02

Health conditions studied

1

Description of health condition studied

Muscular injuries

ICD-10 code

T14.6

ICD-10 code description

Primary disorders of muscles

Primary outcomes

1

Description

Pain

Timepoint

pre and post evaluation

Method of measurement

Numeric pain rating scale (NPRS)

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

2

Description

Stiffness

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 *Mangifera indica* (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 *Mangifera indica* (10%), through superficial massage 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

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

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Multan

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Phone

+92 303 9427506

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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 Road

City

Multan

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+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

50

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,
Multan

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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Agriculture Complex, Old Shuja Abad Rd, Multan,
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Person responsible for scientific inquiries

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Full name of responsible person

Qurat-UI-Ain

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Consultant

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Medical doctor

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Physiotherapy

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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