Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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-Ul- Ain

Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

Country

Pakistan

Phone

+92 303 9427506

Email address

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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 O ther 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 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
Full name of responsible person
Imran Ahmad Khan
Street address
Agriculture Complex, Old Shuja Abad Road
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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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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