

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Formulation of Polyherbal Gel and its Evaluation for Anti-nociceptive and Anti-inflammatory Activities in Sports Injuries with superficial massage and phonophoresis in comparison with diclofenac

Protocol summary

Study aim

This study aimed to evaluate the anti-inflammatory and anti-nociceptive activities of the polyherbal gel consisting of Cinnamomum verum, Curcuma longa, Zingiber officinale, Syzgium aromaticum, Olea europaea, Trachyspermum ammi, Linum usitatissimum, Sesamum indicum, and Mentha piperita, with superficial massage and phonophoresis in comparison with diclofenac diethyl-ammonium.

Design

A pragmatic, community-based study. A single-blinded, randomized controlled trial with a parallel group design of 200 patients, enrolled between March 2022 to August 2022.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Patients already diagnosed with 1st and 2nd grade muscular and soft tissue injuries were included in this study. Patients of either sex, aged 16-70 years who are able to understand the procedure and respond, include in this study. While patients have any type of allergy from the ingredients used for polyherbal gel 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 were excluded from this study.

Intervention groups

Participants were equally distributed into four parallel groups. The first and second groups received topical application of polyherbal gel and diclofenac diethyl-ammonium 1% gel respectively through phonophoresis with therapeutic ultrasound, while the third and fourth groups received topical application of polyherbal 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 Scientific Inquiry and Updating Data was changed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220615055179N1**

Registration date: **2023-01-14, 1401/10/24**

Registration timing: **retrospective**

Last update: **2023-12-16, 1402/09/25**

Update count: **1**

Registration date

2023-01-14, 1401/10/24

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

2022-03-11, 1400/12/20

Expected recruitment end date

2022-08-11, 1401/05/20

Actual recruitment start date

2021-12-15, 1400/09/24

Actual recruitment end date

2022-08-15, 1401/05/24

Trial completion date

2022-08-15, 1401/05/24

Scientific title

Formulation of Polyherbal Gel and its Evaluation for Anti-nociceptive and Anti-inflammatory Activities in Sports Injuries with superficial massage and phonophoresis in comparison with diclofenac

Public title

Formulation of Polyherbal Gel and Evaluation of Anti-nociceptive and Anti-inflammatory Activities

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 for polyherbal gel formulation Skin problem Cancer Diabetic peripheral neuropathy Other neurological disorders Any type of bone fractures Open injuries Patients with casts 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 were equally distributed in four groups. 50 participants in each group.

Actual sample size reached: **50**

More than 1 sample in each individual

Actual sample size in each individual: **50**

Participants were equally distributed in four groups. 50 participants in each group.

Randomization (investigator's opinion)

Randomized

Randomization description

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

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants were blinded

Placebo

Not used

Assignment

Parallel

Other design features

NPRS and WOMAC scales 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

2021-11-10, 1400/08/19

Ethics committee reference number

2021/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 received topical application of polyherbal gel, formulated from aqueous-methanolic (30:70) extracts Cinnamomum verum (2.8%), Curcuma longa (2.8%), Zingiber officinale (1.4%), Syzgium aromaticum (2.8%), Olea europaea (2.8%), Trachyspermum ammi (2.8%), Linum usitatissimum (2.8%), Sesamum indicum (2.8%), and Mentha piperita (1.2%), through phonophoresis with therapeutic ultrasound (continuous mode, 1 MH, 0.8W/cm²), on the affected areas of participants. The gel was used once and the data was collected through Numeric pain rating and The Western Ontario and McMaster Universities Arthritis Index scales.

Category

Treatment - Drugs

2

Description

Intervention group-2: The second group received topical application of polyherbal gel, formulated from aqueous-methanolic (30:70) extracts Cinnamomum verum (2.8%), Curcuma longa (2.8%), Zingiber officinale (1.4%), Syzgium aromaticum (2.8%), Olea europaea (2.8%), Trachyspermum ammi (2.8%), Linum usitatissimum (2.8%), Sesamum indicum (2.8%), and Mentha piperita (1.2%), through superficial massage on effected areas of participants. The gel was used once and the data was collected through NPRS and WOMAC scales.

Category

Treatment - Drugs

3

Description

Control group-1: The third group received diclofenac diethyl-ammonium 1% gel through phonophoresis with therapeutic ultrasound (continuous mode, 1 MH, 0.8W/cm²) on affected areas of participants. The gel was used once and the data was collected through NPRS and WOMAC scales.

Category

Treatment - Drugs

4

Description

Control group-2: The fourth group received diclofenac diethyl-ammonium 1% gel as control group-2 respectively through superficial massage on the affected areas of participants. The gel was used once and the data was 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, Bosan Road, Multan Pakistan

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qain0635@gmail.com

Web page address

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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Multan

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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

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

Agriculture Complex, Old Shuja Abad Road

City

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Province

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asif.raza@edu.pk

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,
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Muhammad Asif Raza

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

Street address**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