Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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-Ul- 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-Ul- Ain
Street address
HBL street, Near Sabzazar Metro Station, Bosan Road, Multan Pakistan
City
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Phone
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Email
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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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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Lecturer
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Medical doctor
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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