

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Formulation and Evaluation of Calotropis gigantea and Curcuma longa spray in Knee Osteoarthritis With And Without Phonophoresis

Protocol summary

Study aim

The study aim to clinically and biochemically assess the effects of Calotropis gigantea and Curcuma longa with and without Phonophoresis in Osteoarthritis.

Design

A pragmatic, community-based study. A single-blinded, randomized controlled trial with a parallel group design of 150 patients, will enroll between August 2023 to September 2023.

Settings and conduct

The study will be conducted at Muhammad Physiotherapy and Rehabilitation Center, Multan, Pakistan. After approval obtained from the Iranian Registry of Clinical Trial and institutional ethical committee.

Participants/Inclusion and exclusion criteria

According to the Kellgren and Lawrence system of grading, patients with the grade 1-2-3 knee osteoarthritis, age 45-70 years of either gender (male and female) will include in this experiment. Patients with neural defects, total knee replacement, RA, injected with steroidal injections in the past 2 years will exclude in this experiment.

Intervention groups

The patients will be engaged after signing the written consent form. The lottery method will be used for grouping of 150 patients into 5 parallel groups (n=30). Group 1 will be treated with test drug with phonophoresis with therapeutic ultrasound (frequency of 0.8MH, and an intensity of about 1.5 W/cm², and with the continuous mode). Group 2 will be treated with test drug with superficial massage. Group 3 will be treated with standard drug piroxicam 0.5% w/w with phonophoresis. Group 4 will be treated with standard drug with superficial massage. Group 5 will be treated with therapeutic ultrasound using aqueous gel as coupling media as placebo or control group. The strengthening exercises like isometrics of quadriceps and isometric exercises of hip adductor muscles will use in 5

groups

Main outcome variables

Pain, stiffness, activities of daily living, and inflammation

General information

Reason for update

The only reason is to update the position of the Person responsible for Scientific Inquiry

Acronym

IRCT registration information

IRCT registration number: **IRCT20220615055179N3**

Registration date: **2023-08-09, 1402/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-23, 1402/09/02**

Update count: **1**

Registration date

2023-08-09, 1402/05/18

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

2023-08-01, 1402/05/10

Expected recruitment end date

2023-09-30, 1402/07/08

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Formulation and Evaluation of Calotropis gigantea and Curcuma longa spray in Knee Osteoarthritis With And Without Phonophoresis

Public title
Formulation and Evaluation of Calotropis gigantea and Curcuma longa spray in Knee Osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
According to the Kellgren and Lawrence system of grading, patients with the grade 1-2-3 knee osteoarthritis Age 45-70 years Both gender
Exclusion criteria:
Neural defects Injected with steroidal injections in the past 2 years Rheumatoid arthritis Total knee replacement

Age
From **45 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **150**
More than 1 sample in each individual
Number of samples in each individual: **30**
Participants will be equally distributed in five groups. 30 participants in each group.

Randomization (investigator's opinion)
Randomized

Randomization description
The lottery method will be used for the randomization of participants into five 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
It is a single blinded study. The data analyser will be kept blind in order to avoid any biasness and for correct authentication and validation of the results.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic's Committee of Muhammad Institute of Medical and Allied Sciences, Multan.

Street address

HBL street, near Sabzazar metro station, Bosan road

City

Multan

Postal code

66000

Approval date

2023-07-10, 1402/04/19

Ethics committee reference number

2023/IRB/7/PT/06

Health conditions studied

1

Description of health condition studied

Osteoarthritis of Knee

ICD-10 code

M17. 9

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Inflammation

Timepoint

Pre (before starting the intervention) and Post evaluation (after 3-4 weeks when treatment sessions/ intervention will be completed depending on different individual and conditions or grades of different individuals)

Method of measurement

Interleukin-6 and Tumor necrotic factor alpha

2

Description

Pain

Timepoint

Pre (before starting the intervention) and Post evaluation (daily after each treatment session, evaluation will be done)

Method of measurement

Numeric pain rating scale (NPRS) and Pain Catastrophizing Scale (PCS)

Secondary outcomes

1

Description

Stiffness, Pain and Activity of daily living

Timepoint

Pre (before starting the intervention) and Post evaluation (after every 3rd session of treatment, evaluation will be done)

Method of measurement

Western Ontario and McMaster Universities Arthritis 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) extracts of *Calotropis gigantea* (20%) and *Curcuma longa* (10%) through phonophoresis with therapeutic ultrasound (frequency of 0.8MH, and an intensity of about 1.5 W/cm², and with the continuous mode) on the affected knee of participants. The gel will be used once.

Category

Treatment - Drugs

2

Description

Intervention group 2: The second group will receive topical application of gel formulated from aqueous-methanolic (30:70) extracts of *Calotropis gigantea* (20%) and *Curcuma longa* (10%) through superficial massage on the affected knee of participants. The gel will be used once.

Category

Treatment - Drugs

3

Description

Control group 1: The third group will receive topical application of standard drug piroxicam 0.5% w/w gel through phonophoresis with therapeutic ultrasound (frequency of 0.8MH, and an intensity of about 1.5 W/cm², and with the continuous mode) on the affected knee of participants. The gel will be used once.

Category

Treatment - Drugs

4

Description

Control group 2: The fourth group will receive topical application of standard drug piroxicam 0.5% w/w gel through superficial massage on the affected knee of participants. The gel will be used once.

Category

Treatment - Drugs

5

Description

Control group 3: The fifth group will be treated with therapeutic ultrasound (frequency of 0.8MH, and an intensity of about 1.5 W/cm², and with the continuous mode) using aqueous gel as coupling media on the affected knee of participants. This will be used once.

Category

Placebo

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

HLB street, near Sabzazar metro station, Bosan road

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Multan

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Phone

+92 303 9427506

Email

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

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+92 333 6120602

Email

imran.ahmad@mnsuam.edu.pk

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

Multan

Province

Punjab

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Person responsible for updating data**Person responsible for general inquiries****Contact****Name of organization / entity**Muhammad Institute of Medical and Allied Sciences,
Multan**Full name of responsible person**

Tehreem Saad Khan

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Contact**Name of organization / entity**Muhammad Institute of Medical and Allied Sciences,
Multan**Full name of responsible person**

Qurat-UI-Ain

Position

Lecturer

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Sharing plan**Person responsible for scientific 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

Street address

Agriculture Complex, Old Shuja Abad Road

City**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