

# 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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/cm<sup>2</sup>, 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

##### City

Multan

##### Postal code

66000

##### 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

##### City

Multan

##### Postal code

66000

##### Phone

+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

**Postal code**

66000

**Phone**

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**Email**

imran.ahmad@mnsuam.edu.pk

**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

**Street address**

HBL street, near Sabzazar metro station, Bosan road

**City**

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**Province**

Punjab

**Postal code**

66000

**Phone**

+92 304 1774786

**Email**

tehreemkhanb1@gmail.com

**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

**Street address**

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**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

qain0635@gmail.com

**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