Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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-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
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-Ul-Ain
Street address
HBL 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

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
Multan
Province
Punjab
Postal code
66000
Phone
+92 304 1774786
Email
tehreemkhanb1@gmail.com

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
Multan
Province
Punjab
Postal code
66000
Phone
+92 333 6120602
Email
imran.ahmad@mnsuam.edu.pk

Person responsible for updating data

Contact
Name of organization / entity
Muhammad Institute of Medical and Allied Sciences, Multan
Full name of responsible person
Qurat-Ul-Ain
Position
Lecturer
Latest degree
Medical doctor
Other areas of specialty/work
Physiotherapy
Street address
HBL street, near Sabzazar metro station, Bosan road
City
Multan
Province
Punjab
Postal code
66000
Phone
+92 303 9427506
Email
qain0635@gmail.com

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