

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Formulation and Evaluation of Brassica oleracea and Zingiber officinale Gel in Knee Osteoarthritis

Protocol summary

Study aim

The study aims to clinically and biochemically assess the effects of Zingiber officinale and Brassica oleracea (cabbage) in patients with knee Osteoarthritis.

Design

A pragmatic, community-based study. A single-blinded, randomized controlled trial with a parallel group design of 375 patients, will enroll between January 2025 to June 2025

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 grade 1-2 knee osteoarthritis, age 40-70 years of either gender (male and female) will be included in this experiment. Patients with neural defects, total knee replacement, RA, injected with steroidal injections in the past 2 years, Tumors in the area of treatment, patients who are not cooperative during the study, and fractures or any other orthopedic condition in the treatment limb will be excluded from this experiment.

Intervention groups

The patients will be engaged after signing the written consent form. The lottery method will be used for grouping, 375 patients into 3 parallel groups (n=125). Group 1 will be treated with a test herbal gel 5% w/w 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 the standard drug piroxicam 0.5% w/w with phonophoresis. Group 3 will be treated with therapeutic ultrasound using aqueous gel as coupling media as a placebo or control group. The proprioceptive neuromuscular facilitation (PNF) stretching and muscle

energy technique (MET) exercises will be used in 3 groups.

Main outcome variables

Pain, stiffness, activities of daily living, and inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220615055179N4**

Registration date: **2024-12-27, 1403/10/07**

Registration timing: **prospective**

Last update: **2024-12-27, 1403/10/07**

Update count: **0**

Registration date

2024-12-27, 1403/10/07

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

2025-01-12, 1403/10/23

Expected recruitment end date

2025-09-10, 1404/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and Evaluation of Brassica oleracea and Zingiber officinale Gel in Knee Osteoarthritis

Public title

Evaluation of Brassica oleracea and Zingiber officinale Gel 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 knee osteoarthritis Both gender Age 40-70 years

Exclusion criteria:

Neural defects Injected with steroidal injections in the past 2 years Rheumatoid arthritis Total knee replacement Tumors in the area of treatment The patients who are not co-operative during the study Fractures or any other orthopedic condition in the treatment limb

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Data analyser

Sample size

Target sample size: **375**

More than 1 sample in each individual

Number of samples in each individual: **125**

Participants will be equally distributed in three groups.

125 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 be written 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 analyzer will be kept blind 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

2024-12-10, 1403/09/20

Ethics committee reference number

2024/IRB/12/Qurat/10

Health conditions studied**1****Description of health condition studied**

Knee Osteoarthritis

ICD-10 code

M17.10

ICD-10 code description

Unilateral primary osteoarthritis, unspecified 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 individuals and conditions or grades of different individuals)

Method of measurement

C-reactive protein (CRP), Interleukin-6, and Erythrocyte Sedimentation Rate (ESR)

2**Description**

Pain

Timepoint

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

Method of measurement

Visual Analog Scale (VAS), Numerical 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

2

Description

Knee joint range of motion

Timepoint

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

Method of measurement

Goniometry

Intervention groups

1

Description

Group 1 will be treated with a test herbal gel 5% w/w with phonophoresis with therapeutic ultrasound (frequency of 0.8MH, and an intensity of about 1.5 W/cm², and with the continuous mode) along with proprioceptive neuromuscular facilitation (PNF) stretching and muscle energy technique (MET) exercises for 3-4 weeks.

Category

Treatment - Drugs

2

Description

Group 2 will be treated with the standard drug piroxicam 0.5% w/w with phonophoresis with therapeutic ultrasound (frequency of 0.8MH, and an intensity of about 1.5 W/cm², and with the continuous mode) along with proprioceptive neuromuscular facilitation (PNF) stretching and muscle energy technique (MET) exercises for 3-4 weeks.

Category

Treatment - Drugs

3

Description

Group 3 will be treated with therapeutic ultrasound using aqueous gel as coupling media as a placebo or control group placebo gel along with proprioceptive neuromuscular facilitation (PNF) stretching and muscle energy technique (MET) exercises for 3-4 weeks.

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

HBL 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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Email

imran.ahmad@mnsuam.edu.pk

Grant name

Student fund

Grant code / Reference number

241290

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, Pakistan

Full name of responsible person

Qurat-UI- Ain

Position

Lecturer

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Position

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Latest degree

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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