

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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/cm<sup>2</sup>, 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

##### 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

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

**Street address**

Muhammad Institute of Medical and Allied Sciences,  
Multan, Pakistan

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**Province**

Punjab

**Postal code**

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qain0635@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**

Lecturer

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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imran.ahmad@mnsuam.edu.pk

## Person responsible for updating data

### Contact

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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