Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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-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

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-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
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-Ul- Ain

Position
Lecturer

Latest degree
Master

Other areas of specialty/work
Physiotherapy

Street address
Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan

City
Multan

Province
Punjab

Postal code
66000

Phone
+92 303 9427506

Email
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

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, Pakistan

Full name of responsible person
Qurat-Ul- Ain

Position
Lecturer

Latest degree
Master

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