Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Formulation and Evaluation of Brassica oleracea and Zingiber officinale Gel in Frozen Shoulder

Protocol summary

Study aim
The study aims to clinically and biochemically assess the effects of Zingiber officinale and Brassica oleracea (cabbage) in patients with Frozen Shoulder.

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
Participants diagnosed with frozen shoulder, aged (30-60 y), limited shoulder r is limited ROM, have experienced pain (NPRS > 4) during movement, and have symptom duration > 3 months will be included in this study. Participants having a history of fracture, infections, inflammatory disorder around the shoulder, any neurological or cardiac conditions, acute or chronic conditions affecting joint mobility, surgical release of capsules, or history of steroidal injection in the affected area will be excluded from this study

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 shoulder mobilization and muscle energy technique (MET) exercises will be used in 3 groups.

Main outcome variables
Pain, stiffness, range of motion, activities of daily living, and inflammation.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220615055179N5**
Registration date: **2025-01-03, 1403/10/14**
Registration timing: **prospective**

Last update: **2025-01-03, 1403/10/14**
Update count: **0**

Registration date
2025-01-03, 1403/10/14

Registrant information

Name
Qurat-Ul- Ain

Name of organization / entity
Muhammad Nawaz Shareef University of Agriculture, Multan

Country
Pakistan

Phone
+92 303 9427506

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quratulain@mimas.edu.pk

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-01-12, 1403/10/23

Expected recruitment end date
2025-06-10, 1404/03/20

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 Frozen Shoulder

Public title
Evaluation of Brassica oleracea and Zingiber officinale Gel in Frozen Shoulder
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Participants diagnosed with frozen shoulder and stiff frozen shoulder Limited shoulder joint range of motion Participants who have experienced pain (NPRS > 4) during movement Age (30- 60 y) Symptom duration > 3 months
Exclusion criteria:
History of fracture around shoulder Inflammatory disorder around shoulder Any neurological condition Cardiac conditions Acute or chronic conditions affecting joint mobility Surgical release of capsules History of steroidal injection in the affected area Patients with joint infection
Age
From **30 years** old to **60 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
2024-12-12, 1403/09/22
Ethics committee reference number
2024/IRB/12/Qurat/12

Health conditions studied

1

Description of health condition studied
Adhesive capsulitis of shoulder
ICD-10 code
M75.0
ICD-10 code description
Adhesive capsulitis of shoulder

Primary outcomes

1

Description
Shoulder 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

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) and Numerical Pain Rating Scale (NPRS)

Secondary 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 other individuals)
Method of measurement
C-reactive protein (CRP) and Erythrocyte Sedimentation Rate (ESR)

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 shoulder mobilization 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 shoulder mobilization 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 shoulder mobilization 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
Ethic's Committee of Muhammad Institute of Medical and Allied Sciences, Multan.
Street address
HBL street, near Sabzazar metro station, Bosan road.
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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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66000
Phone
+92 333 6120602
Email
imran.ahmad@mnsuam.edu.pk
Grant name
Student fund
Grant code / Reference number
241307
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
Full name of responsible person
Qurat-Ul- Ain
Position
Lecturer
Latest degree
Master

Other areas of specialty/work
Physiotherapy
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HBL street, near Sabzazar metro station, Bosan road.
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Person responsible for updating data

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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