

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Formulation And Evaluation of Curcumin Gel Along With Ultrasound and Eccentric Exercises On Patellar Tendinopathy Management

Protocol summary

Study aim

The primary study aim of this study is to investigate the efficacy of an integrative treatment approach combining eccentric exercises with curcumin-enhanced ultrasound therapy for the management of knee tendinopathy.

Design

Pragmatic, community based, parallel group, double blinded, randomised controlled trial. Total 90 patients will be enrolled. Patients who met our inclusion criteria randomised into two groups. Control group-A and treatment group-B

Settings and conduct

At Muhammad Institute of Medical and Allied Sciences Multan after getting approval from institutional ethical committee

Participants/Inclusion and exclusion criteria

Inclusion criteria: Participants between 18 to 60 years of age; patellar tendinopathy, confirmed by a qualified healthcare professional; chronic patellar tendinopathy symptoms for at least 3 months; moderate severity of symptoms; no active inflammatory conditions. Exclusion criteria: Individuals with acute (less than 3 months) patellar tendinopathy or other acute knee injuries; Participants with other significant knee conditions (e.g., patellofemoral pain syndrome, osteoarthritis, ligament injuries, or meniscal tears) that may confound the outcomes or interact with the treatments being tested; surgical interventions involving the patellar tendon or knee in the past 6 months; Individuals with uncontrolled systemic diseases, including rheumatoid arthritis, diabetes mellitus, or severe cardiovascular or neurological conditions that could affect tendon healing or physical activity.

Intervention groups

Control group: Curcumin-aloe vera gel + ultrasound + eccentric exercises. Intervention group: Placebo aloe vera gel + ultrasound + eccentric exercises.

Main outcome variables

Pain, Knee ROM, Muscle strength ,Tendon thickness ,

Quality of life ,CRP, ESR and Tendon function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230202057310N16**

Registration date: **2025-01-22, 1403/11/03**

Registration timing: **registered_while_recruiting**

Last update: **2025-01-22, 1403/11/03**

Update count: **0**

Registration date

2025-01-22, 1403/11/03

Registrant information

Name

Imran Ahmad Khan

Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

Country

Pakistan

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+92 333 6120602

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-01, 1403/10/12

Expected recruitment end date

2025-04-03, 1404/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Formulation And Evaluation of Curcumin Gel Along With Ultrasound and Eccentric Exercises On Patellar Tendinopathy Management

Public title
Curcumin Gel Along With Ultrasound and Eccentric Exercises On Patellar Tendinopathy Management

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Participants between 18 to 60 years of age Clinical diagnosis of patellar tendinopathy, confirmed by a qualified healthcare professional Individuals Experiencing chronic patellar tendinopathy symptoms for at least 3 months Moderate severity of symptoms No active inflammatory conditions (e.g., rheumatoid arthritis) or uncontrolled systemic diseases that might affect tendon healing or the safety of treatments.
Exclusion criteria:
Individuals with acute (less than 3 months) patellar tendinopathy or other acute knee injuries. Participants with other significant knee conditions (e.g., patellofemoral pain syndrome, osteoarthritis, ligament injuries, or meniscal tears) that may confound the outcomes or interact with the treatments being tested Those who have undergone surgical interventions involving the patellar tendon or knee in the past 6 months. Individuals with uncontrolled systemic diseases, including rheumatoid arthritis, diabetes mellitus, or severe cardiovascular or neurological conditions that could affect tendon healing or physical activity.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process will be conducted using computer-generated random numbers to assign participants to treatment groups in a predefined allocation sequence. A stratified or block randomization approach will be used to ensure balance between groups for key variables (e.g., age, gender, baseline disease severity). Medications will be prepared and packaged in identical numbered white boxes according to the allocation sequence. Each box will have a unique medication number corresponding to the assigned

treatment, ensuring blinding. The allocation sequence and treatment codes will be securely stored and accessible only to the principal investigator, who is not involved in participant interactions or outcome assessments.

Blinding (investigator's opinion)
Double blinded

Blinding description
The statistical analyst and outcome assessor will be blinded to treatment allocation by using securely stored randomization codes, accessible only to an independent party. Data will be analyzed using anonymous identifiers, and group allocation will be revealed only after data collection and analysis are complete. This ensures minimization of bias.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Institutional Ethical Committee of Muhammad Institute of Medical and Allied Sciences
Street address
Bosan Road
City
Multan
Postal code
66000

Approval date
2024-11-29, 1403/09/09

Ethics committee reference number
MIMAS/24/08/IAK

Health conditions studied

1

Description of health condition studied
Patellar Tendinopathy
ICD-10 code
M76.50
ICD-10 code description
Patellar tendinitis, unspecified knee

Primary outcomes

1

Description
Pain
Timepoint

Before interventions and 8 weeks after intervention
Method of measurement
Numerical Pain rating scale and Western Ontario and McMaster Universities Osteoarthritis Index

2

Description

Knee range of motion (ROM)

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

Goniometer

3

Description

Tendon thickness

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

ultrasound

4

Description

Tendon function

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

Victorian Institute of Sport Assessment-Achilles (VISA-A)

Secondary outcomes

1

Description

Muscle Strength

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

Hand dynamometer

2

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

Lab test

3

Description

Quality of life

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

SF-36 scale

4

Description

C-Reactive proteins

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

Lab test

Intervention groups

1

Description

Intervention group: Group A: Curcumin-aloe vera gel + ultrasound + eccentric exercises; Ultrasound Application: - Administer therapeutic ultrasound using a frequency of 3 MHz in pulsed mode (intensity of 1-1.5 W/cm²) for 5-10 minutes on the patellar tendon area. Apply curcumin-aloe vera gel before ultrasound therapy to enhance penetration. Treatment frequency: 3 times per week. Focus on slow eccentric loading exercises for the quadriceps, such as decline squats. - Exercise progression: Gradually increase weight/resistance over 8 weeks. - Sessions: 3-4 times per week, supervised by a physiotherapist.

Category

Treatment - Drugs

2

Description

Control group: Group B: Placebo-aloe vera gel + ultrasound + eccentric exercises (Ultrasound Application: - Administer therapeutic ultrasound using a frequency of 3 MHz in pulsed mode (intensity of 1-1.5 W/cm²) for 5-10 minutes on the patellar tendon area. Apply placebo-aloe vera gel before ultrasound therapy to enhance penetration. Treatment frequency: 3 times per week. Focus on slow eccentric loading exercises for the quadriceps, such as decline squats. - Exercise progression: Gradually increase weight/resistance over 8 weeks. - Sessions: 3-4 times per week, supervised by a physiotherapist.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Muhammad physical therapy clinic and rehabilitation center, Multan

Full name of responsible person

Komal Ammar Bukhari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Muhammad Institute of Medical and Allied Sciences,
Multan

Full name of responsible person

Qurat-UI-Ain

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Grant name

Student fund

Grant code / Reference number

MIMAS/25/08/Aroosa

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Muhammad Institute of Medical and Allied Sciences,
Multan

Proportion provided by this source

100

Public or private sector

Private

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

Maliha Khalid Khan

Position

Lecturer

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Name of organization / entity

Muhammad Nawaz Sharif University of Agriculture

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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