Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Oct 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: **2026-09-10, 1405/06/19**
Update count: **1**

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

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Pakistan

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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

Knee range of motion (ROM)

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

Goniometer

2

Description

Tendon thickness

Timepoint

Before interventions and 8 weeks after intervention

Method of measurement

ultrasound

3

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 (Eccentric Exercise + Curcumin–Aloe Vera Gel): Curcumin–aloe vera gel (2 g) will be applied topically to the patellar tendon, followed by a supervised eccentric exercise. The program included wall sits, Spanish squats, box squats, and reverse lunges. All exercises will perform in three sets of 15 repetitions each, at a controlled tempo of 3 seconds eccentric and 1 second concentric. Sessions occurred 4 times per week for 8 weeks, with progressive loading applied biweekly according to pain-free tolerance (0–3/10 NPRS during exercise).

Category

Treatment - Other

2

Description

Control group: Participants will receive2 g of curcumin–aloe vera gel apply topically over the patellar tendon and delivered transdermally using therapeutic ultrasound. Ultrasound will be administered at a frequency of 1 MHz, intensity of 1.5 W/cm², in pulsed mode for 10 minutes using a circular application technique. Treatment will be administered 4 times per week for 8 weeks. No eccentric exercise or other therapeutic exercise will be included in this group to isolate the effect of ultrasound-mediated transdermal delivery of the gel. Adherence will be monitored through clinic attendance registers and self-reported gel application logs.

Category

Treatment - Other

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

Street address

Bosan Road

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+92 312 6827130

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komalbukhari608@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Muhammad Institute of Medical and Allied Sciences, Multan
Full name of responsible person
Qurat-Ul-Ain
Street address
Multan
City
MULTAN
Postal code
66000
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+92 312 6827130
Email
qain0635@gmail.com

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
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Latest degree
Ph.D.
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Medical Pharmacy
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Province
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Person responsible for updating data

Contact
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Bachelor
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aroosajabeen908@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

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