Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Synergistic effect of undenatured collagen type 2 supplementation and knee strengthening exercises in knee osteoarthritis

Protocol summary

Study aim

The study aims to evaluate the comparative effects of undenatured collagen type 2 supplementation, knee strengthening exercise program, on reducing pain and improving joint function in patients with osteoarthritis and degenerative changes.

Design

Pragmatic, community based, parallel group, double blinded, randomized controlled trial. Total 377 patients will be enrolled. Patients who met our inclusion criteria will be randomized into three groups.

Settings and conduct

Muhammad physical therapy clinic and rehabilitation center, Multan.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Adults aged between 35–65 years with mild-to-moderate knee osteoarthritis, knee pain for at least 3 months, able to perform physical activity and follow an exercise regimen, not taking any other osteoarthritis-related medications Exclusion Criteria: Presence of other types of arthritis, history of knee surgery or any intra-articular injections in the past 6 months, currently using immunosuppressive therapy , serious systemic diseases Pregnancy, breastfeeding, known allergy or intolerance to collagen supplements or any ingredients in the intervention product.

Intervention groups

Group 1: Will receive 40 mg/day of undenatured collagen type II supplementation. Group 2: Will be given a standardized knee-strengthening exercise program [specify duration and frequency, e.g., three times per week for 45 minutes]. Group 3: Will recieve UC-II supplementation and participated in the knee-strengthening exercise program..

Main outcome variables

Knee X rays; Western Ontario and McMaster Universities Osteoarthritis Index scale; Numeric Pain Rating Scale; Pain Catastrophizing Scale; Knee Range of Motion (goniometry); Knee injury outcome (KOOS); Muscle strength (dynamometer); Quality of life (SF-36); C-reactive protein; Interleukin-6

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230202057310N11**
Registration date: **2024-12-22, 1403/10/02**
Registration timing: **prospective**

Last update: **2024-12-22, 1403/10/02**
Update count: **0**

Registration date

2024-12-22, 1403/10/02

Registrant information

Name

Imran Ahmad Khan

Name of organization / entity

Muhammad Nawaz Shareef University of Agriculture, Multan

Country

Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-01-05, 1403/10/16

Expected recruitment end date

2025-04-05, 1404/01/16

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Synergistic effect of undenatured collagen type 2 supplementation and knee strengthening exercises in knee osteoarthritis

Public title
Undenatured collagen type 2 supplementation and knee strengthening exercises in knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged between 35–65 years. Diagnosed with mild-to-moderate knee osteoarthritis based on: Radiographic confirmation (Kellgren-Lawrence grade :1–3). Experiencing knee pain for at least 3 months Able to perform physical activity and follow an exercise regimen Willing to take undenatured collagen type II supplementation as prescribed Not taking any other osteoarthritis-related medications or willing to maintain a washout period of at least 2 weeks prior to enrollment Provided written informed consent to participate in the study.
Exclusion criteria:
1. Diagnosed with severe knee osteoarthritis (Kellgren-Lawrence grade 4). History of knee surgery or any intra-articular injections (e.g., corticosteroids, hyaluronic acid) in the past 6 months. Currently using immunosuppressive therapy or corticosteroids Pregnancy, breastfeeding, or planning to become pregnant during the study Presence of serious systemic diseases Known allergy or intolerance to collagen supplements or any ingredients in the intervention product Presence of other types of arthritis such as rheumatoid arthritis, gout, or infectious arthritis.
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
1
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **377**
Randomization (investigator's opinion)
Randomized
Randomization description
This randomization will be done by computer-generated numbers to ensure fairness. Medications will be given in numbered white boxes, each with a unique medication number. The treatment codes will be kept by the principal investigator.
Blinding (investigator's opinion)
Double blinded
Blinding description
Statistical analyser and outcome assessor will be kept blind so that the result obtained will be without biasness.
Placebo
Not 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
2024-11-21, 1403/09/01
Ethics committee reference number
MIMAS/7/91/IAK

Health conditions studied

1

Description of health condition studied
Knee osteroarthritis
ICD-10 code
M19.0
ICD-10 code description
Primary osteoarthritis of other joints

Primary outcomes

1

Description
Osteophytes
Timepoint
12 weeks
Method of measurement
Knee Xray

2

Description
Pain, stiffness and ADLs
Timepoint
12 weeks
Method of measurement
NPRS and WOMAC Scale

3

Description
Knee ROM
Timepoint
12 weeks
Method of measurement
Goniometry

Secondary outcomes

1

Description
Knee injury outcome
Timepoint
12 weeks
Method of measurement
Knee injury outcome score (KOOS)

2

Description
Quality of life
Timepoint
12 weeks
Method of measurement
SF-36

Intervention groups

1

Description
Intervention group: Will receive 40 mg/day of undenatured collagen type II supplementation.
Category
Treatment - Drugs

2

Description
Intervention group: Will be given a standardized knee-strengthening exercise program [specify duration and frequency, e.g., three times per week for 45 minutes].The knee-strengthening exercise program focused on improving muscle strength, joint stability, and functional mobility. It included:• Warm-up: [e.g., 5 minutes of light cycling or walking].• Strengthening exercises: Quadriceps setting, hamstring curls, straight leg raises, and step-ups. Each exercise was performed in sets of 10 repetitions with progressive intensity over the study period.• Cool-down: [specify activities, e.g., 5 minutes of stretching or slow walking].Participants were supervised by trained physiotherapists to ensure adherence and proper technique.
Category
Rehabilitation

3

Description
Intervention group: Will recieve UC-II supplementation and participated in the knee-strengthening exercise program.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Muhammad Rehabilitation Centre, Multan
Full name of responsible person
Komal Ammar Bukhari
Street address
Multan
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komalbukhari608@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan
Full name of responsible person
Qurat Ul Ain
Street address
Bosan Road
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qain0635@gmail.com
Grant name
Student fund
Grant code / Reference number
MIMAS/08/26/Kashifa
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Muhammad Institute of Medical and Allied Sciences, Multan, Pakistan
Proportion provided by this source
70
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

Punjab

Latest degree

Medical doctor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Name of organization / entity

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Position

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Latest degree

Ph.D.

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Medical Pharmacy

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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

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