

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 receive 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 osteoarthritis

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 receive 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

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Multan

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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

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Bosan Road

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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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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