

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The Joint Effects of Turmeric, Black Seeds, Flaxseed and Medicago Sativa for relieving symptoms of knee osteoarthritis: A Phase 1-2 Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Protocol summary

Study aim

Efficacy and safety of Turmeric, Black Seeds, Flaxseed, and Medicago Sativa in patients with osteoarthritis

Design

A Phase 1-2 Randomized, Double-Blind, Placebo-Controlled Clinical Trial. Using balanced block randomization, patients will be enrolled in one of the two groups

Settings and conduct

This study will be conducted in hospitals affiliated with Tabriz University of Medical Sciences. Adults >40 years who have had osteoarthritis for at least 6 months and whose osteoarthritis diagnosis meets the American College of Rheumatology criteria will be eligible. Patients will be instructed to apply the ointment topically three times daily (9 AM, 3 PM, and 9 PM), for up to 12 weeks. Efficacy and safety evaluations of ointments will be done in clinic visits on days 30, 60, and 90 (final visit). Patients will receive boxes with sealed 10-digit codes and will not be aware of the type of judgment received. Doctors, researchers, and those in charge of implementing the project will not know the type of medicine the patients received until the end of the study.

Participants/Inclusion and exclusion criteria

Adults over 40 years of age who have had OA for at least 6 months, and whose OA diagnosis meets the American College of Rheumatology criteria, will be eligible to participate in the present study. Patients will be excluded if there is evidence of other conditions or diseases of the skin or joints, as well as evidence of partial or complete knee joint replacement or anticipated joint replacement in the target knee.

Intervention groups

Two intervention groups (Therapeutic cream: Turmeric, Black Seeds, Flaxseed, and Medicago Sativa and Placebo arm: Placebo cream containing vaseline).

Main outcome variables

The pain, stiffness, and physical function subscales of the Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index, Subject Global Evaluation, and the overall WOMAC score.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220614055167N2**

Registration date: **2023-01-25, 1401/11/05**

Registration timing: **prospective**

Last update: **2023-01-25, 1401/11/05**

Update count: **0**

Registration date

2023-01-25, 1401/11/05

Registrant information

Name

Saeid Safiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3332 7195

Email address

saeidsafiri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-01, 1402/06/10

Expected recruitment end date

2024-09-01, 1403/06/11

Actual recruitment start date

empty	• Investigator
Actual recruitment end date	
empty	Sample size
Trial completion date	Target sample size: 60
empty	Randomization (investigator's opinion)
	Randomized
Scientific title	Randomization description
The Joint Effects of Turmeric, Black Seeds, Flaxseed and Medicago Sativa for relieving symptoms of knee osteoarthritis: A Phase 1-2 Randomized, Double-Blind, Placebo-Controlled Clinical Trial	Using balanced block randomization, patients will be enrolled in one of the two groups, intervention (mixed cream of turmeric, flax seeds, Medicago Sativa, and black seeds) or placebo. The randomization sequence will be performed by an individual who will not participate in the current study. Moreover, the aforementioned randomization method reduces the chances of predicting and manipulating the randomization process and will lead to balanced sample sizes in both groups, both during the study and at the end of the study. The patients will all receive sealed boxes that are numbered with 10-digit codes and contain either the intervention or placebo creams.
Public title	Blinding (investigator's opinion)
Efficacy and safety of Turmeric, Black Seeds, Flaxseed and Medicago Sativa in patients with osteoarthritis	Double blinded
Purpose	Blinding description
Treatment	The patients will receive the boxes sealed with 10-digit codes and in the container of the original drug or placebo, and they will not be aware of the type of drug received, and the researcher will ensure the blinding of the patients. Also, doctors, researchers, and those responsible for the implementation of the project will not be aware of the type of medicine received by the patients until the end of the study.
Inclusion/Exclusion criteria	Placebo
Inclusion criteria:	Used
At least 6 months of diagnosis of knee osteoarthritis, and whose OA diagnosis meets the American College of Rheumatology criteria Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) pain subscale baseline value of ≥ 9 (0-20 scale) Functional Capacity Classification of I-III Radiograph evidence of OA in the target knee with a Kellgren-Lawrence score of 2 or 3 Morning stiffness of <30 min duration or crepitus on active motion, which is present upon examination	Assignment
Exclusion criteria:	Parallel
Evidence of other conditions or diseases of the skin or joints Evidence of partial or complete knee joint replacement or anticipated joint replacement in the target knee Contraindications to the use of non-steroidal anti-inflammatory drugs (NSAIDs) or who use anticoagulant therapy that prohibits them from using NSAIDs Pregnancy, planning to become pregnant or breastfeeding during the study period Ischemic heart disease, heart failure, end-stage cirrhosis, end-stage renal failure, or psychiatric conditions that prevent an adequate evaluation of the study outcomes Insufficient cognitive functioning to participate and complete the questionnaires Unable or unwilling to follow up and complete the study pathway, A history or diagnosis of other arthritic conditions, such as rheumatoid arthritis, joint and bone deformities, fibromyalgia and/or other inflammatory and immune system disorders Type I or II diabetes or obesity (body mass index ≥ 39) Suffering from painful conditions or frequent headaches requiring the use of systemic opiates or derivatives, or the need for additional NSAID or COX-2 inhibitors Receiving systemic or intra-articular corticosteroid injections. Having active cancer undergoing treatment that prevents the evaluation of the outcome measures	Other design features
Age	
From 40 years old	Secondary Ids
Gender	empty
Both	Ethics committees
Phase	1
1-2	Ethics committee
Groups that have been masked	Name of ethics committee
• Participant	Ethics committee of Tabriz University of Medical Sciences
• Care provider	Street address
	Azadi St., Golgasht Ave., Tabriz University of Medical Sciences
	City
	Tabriz
	Province
	East Azarbaijan
	Postal code
	5166616471
	Approval date
	2023-01-09, 1401/10/19
	Ethics committee reference number
	IR.TBZMED.REC.1401.912

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.9

ICD-10 code description

Osteoarthritis of knee, unspecified

Primary outcomes

1

Description

Joint pain

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index pain, joint stiffness and physical function subscales

2

Description

Joint stiffness

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index pain, joint stiffness and physical function subscales

3

Description

Physical function

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index pain, joint stiffness and physical function subscales

4

Description

Overall Western Ontario and McMaster Universities Osteoarthritis score

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

5

Description

Subjective Global Evaluation (SGE)

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

Subjective Global Evaluation forms

Secondary outcomes

1

Description

Quality of life

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

Evaluation of patient's quality of life, which will be measured using the 36-Item Short Form Survey which produces Mental Component and Physical Component scores

2

Description

Quality of sleep

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

The quality of sleep, which will be measured using the Pittsburgh Sleep Quality Index.

3

Description

Functional Capacity Classification

Timepoint

Day 0, 30, 60, 90 post intervention

Method of measurement

Functional Capacity Classification will be evaluated using a 4-point Likert scale and will be evaluated by the doctor and placed into 4 classes (Class I-IV), which range from full functional capacity to disabled.

Intervention groups

1

Description

Intervention group: Cream containing Turmeric, Black Seeds, Flaxseed, and Medicago Sativa

Category

Treatment - Drugs

2

Description

Control group: Vaseline cream

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Sciences

Full name of responsible person

Saeid Safiri

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Golgasht St.

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5166/15731

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Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Fax**Email**

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Province

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5155668474

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

80

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 scientific inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Saeid Safiri

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Person responsible for updating data**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

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Latest degree

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Other areas of specialty/work

Epidemiology

Street address**Person responsible for general inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no additional information.

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All of the information will be available to all after publishing without the personal information of participants.

When the data will become available and for how long

After publishing the papers

To whom data/document is available

All researchers that are confirmed by the principal investigator

Under which criteria data/document could be used

All of the data will be available except the personal information of the participants

From where data/document is obtainable

The principal investigator

What processes are involved for a request to access data/document

After sending the request by e-mail to the principal investigator, the requests will be evaluated by the team within one month, and if it is approved by the members, the requested information will be sent within three to four months from the time of the request.

Comments