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

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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

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

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

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

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

Exclusion criteria:

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

Age

From **40 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

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.

Blinding (investigator's opinion)

Double blinded

Blinding description

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.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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 general inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
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Saeid Safiri
Position
Assistant Professor
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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