# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## The effect of oral black seed oil capsule on serum level of Tenascin-C in knee osteoarthritis patients

## Protocol summary

**Study aim**

Investigating the effect of oral black seed oil capsules on the serum level of tenascin C biomarker in patients with knee osteoarthritis

**Design**

The clinical trial with a control and intervention group, will conducte in parallel and three-blind, randomized by simple randomization method using closed door envelope , and it will be phase 2-3 clinical trial study on 80 patients.

**Settings and conduct**

A study will be conducted on 80 patients with osteoarthritis of the knee referred to the rheumatology clinic of Qaim Hospital in Mashhad. which are placed in the intervention and control groups in a parallel three-way blind way (participant, evaluators and analysts). Oral black seed capsules in the intervention group and placebo in the control group will be consumed twice a day for 3 months, and the effect of this intervention on the tenascin-C serum level and the amount of pain in the knee area will be investigated.

**Participants/Inclusion and exclusion criteria**

The main condition for entering the study is knee osteoarthritis and Informed consent Not suffering from primary inflammatory disease in the knee joint or arthritis caused by intra-articular tumor crystals Not previous intra-articular fracture of the knee joint surgery (arthroscopic or otherwise) in the last 12 months The absence of simultaneous severe diseases (metabolic diseases and history of stroke in the past)

**Intervention groups**

Intervention group: Patients will take two black seed capsules per day (every 12 hours) for 3 months, control group: patients will take two placebo capsules per day (every 12 hours) for 3 months; Medicine and placebo are prepared by Barij Essan Company, which are used along with the routine treatment of osteoarthritis which is the use of non-steroidal anti-inflammatory drugs in case of pain.

**Main outcome variables**

The amount of pain in the knee Tenascin-C serum level

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20210923052559N1**
Registration date: **2022-10-11, 1401/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-11, 1401/07/19**
Update count: **0**

**Registration date**

2022-10-11, 1401/07/19

**Registrant information**

**Name**

Farzaneh Iravani

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-09-23, 1401/07/01

**Expected recruitment end date**

2022-12-22, 1401/10/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
The effect of oral black seed oil capsule on serum level of Tenascin-C in knee osteoarthritis patients

**Public title**
The effect of oral black seed oil on knee osteoarthritis
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Knee osteoarthritis Satisfaction to enter the study
**Exclusion criteria:**
Taking medicine for osteoarthritis of the knee Having an infection or primary inflammatory disease in the knee joint Arthritis caused by crystals Intra-articular tumors Knee joint ligament instability Previous intra-articular fracture Knee joint surgery (arthroscopic or otherwise) in the last 12 months Injection of any intra-articular drug in the last 3 months Existence of simultaneous severe diseases (metabolic diseases and history of stroke in the past)
**Age**
No age limit
**Gender**
Both

**Phase**
2-3
**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **80**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Simple randomization will be done by www.randomization.com website . Numbers will be placed in sealed envelopes and each envelope is assigned to one participant placing them in one of the two groups.
**Blinding (investigator's opinion)**
Triple blinded
**Blinding description**
The study subjects and those who evaluate the outcome in the participants as well as the final analyst of the collected data of the study will be unaware of the intervention and control groups due to the fact that the placebo is used in the study in parallel with the drug.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Mashhad University of Medical Sciences
**Street address**
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah Street
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
9138813944
**Approval date**
2022-07-12, 1401/04/21
**Ethics committee reference number**
IR.MUMS.MEDICAL.REC.1401.319

## Health conditions studied

### 1

**Description of health condition studied**
Knee osteoarthritis
**ICD-10 code**
M19.9
**ICD-10 code description**
Osteoarthritis, unspecified site

## Primary outcomes

### 1

**Description**
The amount of pain in the knee area
**Timepoint**
At the beginning of the study (before the start of the intervention) and 1, 2 and 3 months after the start of black seed oil capsules
**Method of measurement**
WOMAC questionnaire

### 2

**Description**
Tenascin-C serum level
**Timepoint**
At the beginning of the study (before the start of intervention) and 3 months after the start of taking black seed oil capsules
**Method of measurement**
ELISA method using the Tenascin-c kit from Zellbio GmbH company

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: Patients in this group will take two black seed capsules per day (every 12 hours) for 3 months.Each capsule of black seed contains 5.3 mg of thymoquinone, the effective dose of which has anti-inflammatory effects and reduces the destruction of cartilage.The drug is prepared by Barij Essan Company.In addition to the routine treatment of osteoarthritis, which is the use of non-steroidal anti-inflammatory drugs in case of pain.

**Category**
Treatment - Drugs

### 2

**Description**
Control group: Patients in this group will take two placebo capsules (it will look similar to the medicine capsule) per day (every 12 hours) for 3 months.Placebo is also prepared by Barij Essan Company.In addition to the routine treatment of osteoarthritis, which is the use of non-steroidal anti-inflammatory drugs in case of pain.

**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Ghaem hospital

**Full name of responsible person**
Mandana Khodashahi

**Street address**
Ghaem hospital, Ahmad Abad Ave

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Khodashahim@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Mashhad University of Medical Sciences

**Full name of responsible person**
Dr Majid Ghayour Mobarhan

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Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes

**Title of funding source**
Mashhad University of Medical Sciences

**Proportion provided by this source**
100

**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**
Mashhad University of Medical Sciences

**Full name of responsible person**
Mandana Khodashahi

**Position**
Associate professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Internal Medicine

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Email**
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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**
No - There is not a plan to make this available
**Statistical Analysis Plan**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
No - There is not a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available