Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 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
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Iran (Islamic Republic of)
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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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
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 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
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