

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effects of oral *Nigella sativa* seed oil on osteoarthritis indexes in patients suffering from knee osteoarthritis

Protocol summary

Study aim

The effect of *Nigella sativa* oil on the improvement of pain, joint stiffness and physical activity symptoms in patients with knee osteoarthritis

Design

This clinical trial study will be conducted in a double-blind, phase 2 -3 clinical trial on 80 knee osteoarthritis patients. Patients are randomly divided into two parallel groups. The patients fill the questionnaire sheet and receive the *Nigella sativa* oil or placebo emulsion and Identification code (A or B) are recorded in the patient's medical records.

Settings and conduct

The knee osteoarthritis patients referring to Baghiatallah Hospital according to inclusion criteria randomly divided to *Nigella sativa* or placebo groups. Except main investigator, non of the medical staff, patients, data collector and who evaluate the outcome, are unaware of the medication type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male or female 50 to 70 years old patients with knee osteoarthritis intensity of 1 or 2.

Exclusion criteria: Patients with secondary osteoarthritis, serious systemic disease and history of any other chronic inflammatory disease; history of arthroscopic, surgery, knee replacement; pregnant and breast-feeding women

Intervention groups

Nigella sativa oil: patients taking a tablespoon of *Nigella sativa* oil emulsion three times a day after food. Placebo: patients taking a tablespoon of placebo emulsion three times a day after food.

Main outcome variables

1- Pain intensity using Visual Analog Scale questionnaire and 2- Arthritis Index, joint stiffness and physical activity using Western Ontario and McMaster Universities Arthritis Index questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001157N13**

Registration date: **2018-03-27, 1397/01/07**

Registration timing: **prospective**

Last update: **2018-06-03, 1397/03/13**

Update count: **1**

Registration date

2018-03-27, 1397/01/07

Registrant information

Name

Hasan Fallah Huseini

Name of organization / entity

Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26 3476 4010

Email address

fallah@imp.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-20, 1397/01/31

Expected recruitment end date

2019-12-22, 1398/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of oral Nigella sativa seed oil on osteoarthritis indexes in patients suffering from knee osteoarthritis

Public title

Effect of Nigella sativa oil on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male or female patients with knee osteoarthritis 1 or 2 intensity according to physical examination and knee joint radiography Age 50 to 70 years Exacerbation of the disease at a rate of at least 2 units of sub-total pain score after discontinuation of analgesic drugs which was used at least 3 days a week during the last month A minimum of 9 points out of 20 for pain, joint stiffness and physical activity of the patient according to the criteria of Western Ontario and McMaster Universities pain subscale index after discontinuing analgesic drug medications

Exclusion criteria:

Patients with secondary osteoarthritis due to a known disease Patients with history of arthroscopy, surgery, knee replacement and injection to the knee joint during the last 6 months Any serious systemic disease and other chronic inflammatory disease Patients receiving steroid anti-inflammatory drugs, muscle relaxant, antidepressants, glucosamine, chondroitin, tramadol, topical analgesic agents Like the capsaicin Alcohol consuming and drug abuse patients Patients who refuse to stop analgesic drugs No flares after discontinuation of analgesic drugs that using at least 3 days a week during the last months Breast-feeding, pregnant women and who intend to have children

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, a random number table and block randomization method is used. In this method, eligible patients are divided into blocks of 4 patients. There is no significant difference between the patients in each block in terms of total pain score index. To half of the patients in a block, from the random numbers table, the numbers whose first digits are even and to other half patients, the numbers that first digit are odd are allocated. Then, half of the patients in the block which the first digit are even the Nigella sativa oil are assigned and the other half of

the patients which the first digit are odd are assigned to the placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

Letters A or B are labeled on drug or placebo emulsion bottles. Other specifications on the labels are completely identical. Physician, nurse, patient, data collector and those who evaluate the outcome, are unaware of the nature and meaning of the letters A or B on the labels. Only the main investigator knows the nature of the labels. Patients are aware that they are either in the drug or in the placebo groups, but they are not aware of the type of group they are in.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Avicenna research institute

Street address

Rashidodin Fazlolah Street, Yaman Ave, Shaheed Chamran Highway, Evin

City

Tehran

Province

Tehran

Postal code

1177-19615

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

IR.ACECR.Avicenanna.REC.1396.26

Health conditions studied**1****Description of health condition studied**

Osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Osteoarthritis, unspecified site

Primary outcomes**1****Description**

Severity of arthritis

Timepoint

Before and end of intervention after 1 month

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index Questionnaire

2

Description

Extent of joint pain

Timepoint

Before and end of intervention after 1 month

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index Questionnaire

3

Description

Extent of joint stiffness

Timepoint

Before and end of intervention after 1 month

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index Questionnaire

4

Description

Extent of physical function

Timepoint

Before and end of intervention after 1 month

Method of measurement

The Western Ontario and McMaster Universities Arthritis Index Questionnaire

Secondary outcomes

1

Description

Dose of acetaminophen used

Timepoint

Before intervention and after 1 month at end of the intervention

Method of measurement

Daily recording of the acetaminophen dose used by the patient

2

Description

Pain intensity

Timepoint

Before and end of the study and after one month

Method of measurement

Visual Analog Scale questionnaire

Intervention groups

1

Description

Intervention group: Nigella sativa oil emulsion; Patients taking a tablespoon of nigella sativa oil emulsion three times a day after food (5 ml nigella sativa oil daily) for one month.

Category

Treatment - Drugs

2

Description

Placebo group: Placebo emulsion; Patients taking a tablespoon of placebo emulsion three times a day after food (total 5 ml mineral oil taking per day) for one month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiatallah Hospital

Full name of responsible person

Reza Mohtashami

Street address

Mollasadra Street, Vanak Square

City

Tehran

Province

Tehran

Postal code

1360136023

Phone

+98 21 2558

Email

reza_mohtashami1979@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Reza Hajiaghaee

Street address

Kavosh Boulevard, Supa Boulevard, 55th km of Tehran-Qazvin Highway, Research Complex of Jahad Daneshgahi

City

karaj

Province

Alborz

Postal code

13601360

Phone
+98 26 3476 4010

Fax
+98 26 3476 4021

Email
huseini_fallah@yahoo.com

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

Title of funding source
Iranian academic center for education culture and research

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

Iranian academic center for education culture and research

Full name of responsible person

Fallah Huseini Hasan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Institute of Medicinal Plants, ACECR Complex, Supa Boulevard, Poleh Kordan

City

Karaj

Province

Alborz

Postal code

3365166571

Phone

+98 26 3476 4010

Fax

+98 26 3476 4021

Email

h.fallah@acecr.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Reza Mohtashami

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Vanak square, Molasadra Ave, Baqiyatallah University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1484958693

Phone

+98 21 8806 8923

Fax

+98 21 8806 8923

Email

reza_mohtashami1979@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Hasan Fallah Huseini

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Research Complex of Jihad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55-kilometer of the Tehran-Qazvin Highway

City

karaj

Province

Alborz

Postal code

3365166571

Phone

+98 26 3476 4010

Email

huseini_fallah@yahoo.com

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

No - There is not 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

No - There is not a plan to make this available