Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 sative 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 stuff, 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 Jahad 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