Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of oral administration and topical application of black seed oil (Nigella Sativa) on pain, function and serum indices of inflammation and oxidative stress in patients with knee osteoarthritis

Protocol summary

Study aim

Determination of oral administration and topical application of black seed oil on pain, function and serum indices of inflammation and oxidative stress in patient with knee osteoarthritis.

Design

This study is a randomized double blind phase 2 clinical trial in 45 patient with knee osteoarthritis.Participants will randomly be assigned in to 3 groups to take oral and topical nigela saliva oil and placebo.

Settings and conduct

Target population are all patient with moderate knee osteoarthritis that referred to the specialized clinics of Tabriz university of medical science.Sampling will be done by convenience non randomized method.To concealed the allocation , the same pack which numbered sequentially will be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria include moderate knee osteoarthritis. Exclusion criteria include rhomatologic disease;history of surgery on knee joint;history of lower limbs fracture which is affected knee joint surface;severe knee osteoarthritis;patient with neuropathy,skin rash and ulcer at knee area.

Intervention groups

Participants will be randomly divided into three groups to receive 1)oral black seed oil 2)topical black seed oil and 3)placebo.In group 1, 2.5 ml of oral black seed BID and topical placebo oil.In group 2, topical black seed oil and oral placebo oil, and in group 3, 2.5 ml of oral placebo oil and topical placebo oil will receive.

Main outcome variables

Pain severity, osteoarthritis index, mobility, serum inflammatory index, serum indices of oxidative stress

General information

Reason for update

Update the start time of the participants' recruitment

Acronym

IRCT registration information

IRCT registration number: **IRCT20081004001292N5**
Registration date: **2019-01-22, 1397/11/02**
Registration timing: **prospective**

Last update: **2021-11-02, 1400/08/11**
Update count: **1**

Registration date

2019-01-22, 1397/11/02

Registrant information

Name
Vahideh Toopchizadeh
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-23, 1399/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of oral administration and topical application of black seed oil (Nigella Sativa) on pain, function and serum indices of inflammation and oxidative stress in patients with knee osteoarthritis

Public title
The effect of of black seed oil on knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Moderate knee osteoarthritis

Exclusion criteria:
Rheumatologic disorder such as rheumatoid arthritis History of knee joint surgery History of lower limb bone fracture which encounter knee joint surface Severe knee osteoarthritis Neuropathic or sensory disorders Cutaneous disorder at knee area

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be allocated randomly using random blocking method using blocks 8 and 12 and RASS software and 1: 1: 1 allocation ratio to three groups: (1) oral nigella sativa oil, (2) topical nigella sativa oil, 3) placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
To randomize a random number table and block randomization method will be use. In this method, eligible patients are divided into blocks of 15 patients.The members of the first group are given supplemental edible therapy with black seed oil and topical placebo oil. The second group uses the black seed oil as topical and edible placebo oil, and the third group or the control group receive placebo edible oil as well as topical placebo oil.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Regional Ethics Committee of Tabriz University of Medical Sciences

Street address
Vice Chancellor for research, Tabriz University of Medical Sciences, Golgasht Str.

City
Tabriz

Province
East Azarbaijan

Postal code
5166614756

Approval date
2017-03-01, 1395/12/11

Ethics committee reference number
IR.TBZMED.REC.1395.1291

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis

ICD-10 code
M19.8

ICD-10 code description
Other specified arthrosis

Primary outcomes

1

Description
Pain severity

Timepoint
Evaluating the pain scale at the beginning of the study (before intervention) and six weeks after the intervention began.

Method of measurement
Visual Analogue Scale

2

Description
Osteoarthritis index

Timepoint
Evaluating activity at the beginning of the study (before intervention) and six weeks after the intervention began.

Method of measurement
The Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

3

Description
Mobility
Timepoint
Evaluating mobility at the beginning of the study and six weeks after the intervention began.
Method of measurement
Time up and go test

4

Description
Serum inflammatory high-sensitivity C-reactive protein index
Timepoint
Measuring serum level of C-reactive protein inflammatory factor at the beginning of the study and six weeks after the intervention began.
Method of measurement
Biochemical assay

5

Description
Serum stress oxidative index
Timepoint
Measuring serum level of total antioxidant capacity and 3,4-Methylenedioxyamphetamine at the beginning of the study and six weeks after the intervention began.
Method of measurement
Biochemical assay

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: Edible Nigella Sativa oil manufactured by Barij essence's pharmaceutical company, 2.5 ml twice a day in addition topical placebo oil containing paraffin manufactured by Farabi's pharmaceutical company, which is in shape, smell and other appearance characteristics quite similar to the Nigella Sativa oil, topically twice a day for 45 days.
Category
Treatment - Drugs

2

Description
Second intervention group: Topical Nigella Sativa oil manufactured by Barij essence's pharmaceutical company, twice a day in addition edible placebo oil containing paraffin manufactured by Farabi's pharmaceutical company, which is in shape, taste, smell and other appearance characteristics quite similar to the Nigella Sativa oil, 2.5 ml twice a day for 45 days.
Category
Treatment - Drugs

3

Description
Control group: Edible placebo oil containing paraffin manufactured by Farabi's pharmaceutical company,which is in shape, taste, smell and other appearance characteristics quite similar to the Nigella Sativa oil, 2.5 ml twice a day in addition topical placebo oil containing paraffin manufactured by Farabi's pharmaceutical company, which is in shape, smell and other appearance characteristics quite similar to the Nigella Sativa oil, topically twice a day for 45 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
Vahideh Toopchizade
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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?
No
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Neda Dolatkhah
Position
Assistant Professor
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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
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
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
Undecided - It is not yet known if there will be a plan to make this available