Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Survey on oral administration of Nigella sativa L. on relieving clinical symptoms of knee osteoarthritis: a randomized double- blinded placebo-controlled clinical trial. Phase II: Evaluation of treatment response & safety of oral administration of nigella sativa.

Protocol summary

Summary

The goal of this randomized , double blind , placebo controlled and parallel design clinical study, is to evaluate oral administration of Nigella Sativa, on knee osteoarthritis ,in knee OA patients attending rheumatology clinic of Sina hospital, Tehran University of Medical Sciences . Inclusion criteria is: a minimum of 40 and maximum age of 69 years ,having the radiological and clinical knee OA ACR criteria, and the pain score> 40 mm on VAS scale. patients with a sample size of 60 patients in both two groups ,enter the study.Intervention:Nigella Sativa, and placebo : starch , both in capsules (500mg,2 before breakfast & 1 before lunch & dinner) are given to patients for 12 weeks .acetaminophen up to 4 gr/day is considered as the rescue medicine. During the study outcomes including: Pain , Other symptoms, Function in daily living, Function in Sport and Recreation ,and knee-related Quality of Life that are measured by KOOS scale, the global patient & physician assessment that are measured by VAS scale, the number of acetaminophen tablets taken ,and the laboratory and clinical drug side effects , that are checked at weeks 2 , 4, 8 and 12 .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111515408N1**
Registration date: **2013-12-20, 1392/09/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-12-20, 1392/09/29

Registrant information

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Recruitment status

Recruitment complete

Funding source

School of Traditional Medicine Traditional Medicine and Materia Medica Research Center Shahid Beheshti University of Medical Sciences.

Expected recruitment start date

2013-12-21, 1392/09/30

Expected recruitment end date

2014-03-19, 1392/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey on oral administration of Nigella sativa L. on relieving clinical symptoms of knee osteoarthritis: a randomized double- blinded placebo-controlled clinical trial. Phase II: Evaluation of treatment response & safety of oral administration of nigella sativa.

Public title
Survey on oral administration of black cumin on relieving clinical symptoms of knee osteoarthritis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria : Patients greater than 40 and less than 80 years old who have ACR clinical and radiological ACR criteria and VAS> 40mm after a drug wash out period . Radiological ACR criteria include : □ knee pain plus at least One of four following criteria □ □ 50 years of age, morning stiffness less than 30 minutes □ □crepitus osteophytes. exclusion criteria : 1 . History of rheumatoid arthritis , gout , CPPD 2. Previous surgery on the affected knee 3 .Severe cardiovascular disease grade 3 and 4.4 . malignancy.5 . Liver disease (bleeding esophageal varices , encephalopathy , ascites) 6 . Symptomatic gallstone (in history) 7 . Severe renal disease (serum creatinine 3 mg / dl) 8.administration of oral corticosteroid 4 weeks before 9 . More than 325 mg daily NSAID intake 10 . receiving any central nervous system depressant , including benzodiazepines , barbiturates and narcotics 11. Intra-articular treatment received 3 months ago.12 .Intaking Piaschledine or glucosamine . 13.Not tendency for drug taking. 14. Lack of willingness or ability of patients to complete the questionnaire used in the study. 15 . Older than 79 years .16. Pregnancy and lactation. 17 . patients with a history of asthma or respiratory allergies . 18. patients receiving insulin.19. . Patients receiving warfarin , clopidogrel 20 . Or any other medications that is not permitted , according to pharmacologist's view. 21 . Lack of persistence of above Nineteen . 22 . Patient's unwillingness to continue participation in the study. 23 . Occurrence of any of the threatening side effects that maybe don't predicted.
Age
From **40 years** old to **69 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Office of Research Affairs, Deputy of Research and Technology, Shahid Beheshti University of Medical
Street address
Sixth Floor, College Staff Building Number Two, Shahid Beheshti University of Medical Sciences, next to Taleghani Hospital, Parvaneh st., Yemen st., Shahid Chamran Highway.
City
Tehran
Postal code
Approval date
2013-09-08, 1392/06/17
Ethics committee reference number
138

Health conditions studied

1

Description of health condition studied
knee osteoarthritis
ICD-10 code
M17.9
ICD-10 code description
Gonarthrosis, unspecified

Primary outcomes

1

Description
Pain
Timepoint
before the intervention,weeks 2,4,8 & 12 After intervention
Method of measurement
KOOS Pain

Secondary outcomes

1

Description
Function in daily living
Timepoint
before interventin & weeks 2,4,8,12 after intervention.
Method of measurement
KOOS ADL

2

Description
other Symptoms
Timepoint
before interventin & weeks 2,4,8,12 after intervention.

Method of measurement
KOOS Symptoms

3

Description
Function in Sport and Recreation
Timepoint
before interventin & weeks 2,4,8,12 after intervention.
Method of measurement
KOOS Sport/Rec

4

Description
knee-related Quality of Life
Timepoint
before interventin & weeks 2,4,8,12 after intervention.
Method of measurement
KOOS QOL

5

Description
Globall physition assessment of treatment
Timepoint
weeks 2,4,8 &12
Method of measurement
VAS

6

Description
Globall patient assessment of treatment
Timepoint
weeks 2,4,8 &12
Method of measurement
VAS

7

Description
Number of acetaminophen tablets used
Timepoint
weeks 2,4,8 &12
Method of measurement
Question from patient

Intervention groups

1

Description
intervention group:2 cap.500 mg of modabbar black cumin, , 20 " before breakfast & 1 before lunch & dinner, for 12 weeks.
Category
Treatment - Drugs

2

Description
for both intervention & control group: tablet 500 mg, PRN, up to 4 gr/day for 12 weeks.
Category
Treatment - Other

3

Description
control group:2 cap.500 mg of starch , 20 " before breakfast & 1 before lunch & dinner, for 12 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Research Center, Tehran University of Medical Sciences, Sina General Hospital.
Full name of responsible person
Ahmad Salimzadeh,M.D, Rheumatologist, Associate Professorl
Street address
Rheumatology Research Center, Tehran University of Medical Sciences, Sina General Hospit, Imam Khomeini Ave., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center,Shahid Behes
Full name of responsible person
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No.8 Shams Alley, opposite St tavanir, Vali Asr Street, Tehran
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Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
School of Traditional Medicine, Traditional Medicine and Materia Medica Research Center,Shahid Behes
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty