

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effect of topical application of black cumin oil and diclofenac sodium topical gel on elderly knee pain

Protocol summary

Summary

The aim of this study is to compare the effect of topical application of diclofenac Black cumin (*Nigella sativa*) oil on knee joint pain of elderly. The population of this study was consisted of women and men aged 60 to 80 years old who referred to traditional medicine Salamatkadeh (traditional medicine Health compartment) affiliated by Sabzevar University of Medical Sciences. Sample size: 52 patients with knee joint pain. The study was a double-blind clinical trial with Intervention (black cumin oil) and Control (diclofenac gel) groups. The subjects were not aware of the choice of the type of the study group. Easy sampling was performed and then random allocation was done by permutation blocking method. Topical application of drugs was performed twice a day for 21 days. Inclusion criteria: being at the age of 60 to 80 years old; diagnosis of knee Osteoarthritis according to American College Rheumatologic Diagnostic Criteria; Crepitus; morning knee stiffness less than 30 minutes; and inflammation in the knee examination, Exclusion criteria: cancer; Addiction; treatment with corticosteroids and glucosamine; blindness and Deafness and lack of communication. Primary outcome variable: knee pain; pain intensity; pain quality; pain time; joint stiffness; daily activities; recreational activities. Secondary outcome variable: adverse drug reaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017080835563N1**

Registration date: **2017-10-27, 1396/08/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-27, 1396/08/05

Registrant information

Name

Fatemeh Azizi

Name of organization / entity

Sabzevar University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of topical application of black cumin oil and diclofenac sodium topical gel on elderly knee pain

Public title

The effect of black cumin oil on Knee joints pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: being at the age of 60 to 80 years old;

diagnosis of knee Osteoarthritis according to American College Rheumatologic Diagnostic Criteria; Crepitus; morning knee stiffness less than 30 minutes; ; Knee osteoarthritis was confirmed by a physician and radiographic evidence; inflammation in the knee examination. Exclusion criteria: blindness and Deafness and lack of communication; cancer; Addiction; treatment with corticosteroids and glucosamine.

Age

From **60 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Random allocation was done by permutation blocking method.

Secondary Ids**1****Registry name**

-

Secondary trial Id

-

Registration date

empty

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

Ethics committee of Sabzevar University of Medical Sciences

Street address

Medical campus, Sabzevar University of Medical Sciences, Daneshgah boulevard Sabzevar

City

Sabzevar

Postal code

9613873136

Approval date

2017-08-14, 1396/05/23

Ethics committee reference number

IR.MEDSAB.REC.1396.47

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

knee joint pain

ICD-10 code

M25.5

ICD-10 code description

Pain in joint

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

Knee joint pain

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

2**Description**

Intensity of pain

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

3**Description**

Pain quality

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

4**Description**

Pain time

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

5**Description**

Joint stiffness

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

6**Description**

daily activities

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

7**Description**

Recreational activities

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

8**Description**

Quality of Life

Timepoint

Before the study - 10 days after the study - 21st day and the end of the study

Method of measurement

knee injury and osteoarthritis outcom score(koos)

Secondary outcomes**1****Description**

Advers drug reaction

Timepoint

Every week after the beginning of the study, one week after the end of the study

Method of measurement

Patient's report

Intervention groups**1****Description**

Control group: topical application of diclofenac sodium gel 1% (2 g in the morning and at night for 21 days, produced by Tehran Razak Company.

Category

Treatment - Drugs

2**Description**

Intervention group: Local application of black cumin oil (1 cc in the morning and night) for 21 days from the Isfahan Ganjineh osare Tabiat pharmaceutical company.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Traditional Medicine Health Center, Sabzevar University of Medical Sciences

Full name of responsible person

Fatemeh Azizi Nursing Graduate Student

Street address

Health Center of Sabzevar University of Medical Sciences, Asad Abadi Street

City

Sabzevar

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Sabzevar University of Medical Sciences

Full name of responsible person

Dr. Fereshteh Ghorat

Street address

Medical campus, Sabzevar University of Medical Sciences, Daneshgah boulevard

City

Sbzevar

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

Yes

Title of funding source

Vice Chancellor for research of Sabzevar University of Medical Sciences

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****Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Fatemeh Azizi

Position

Nursing Graduate Student

Other areas of specialty/work

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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