Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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

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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 injery 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 injery 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 injery 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 injery 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 injery 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 injery 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 injery 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 injery 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

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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