Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of topical poppy oil on pain relief in patients with severe osteoarthritis of knee: randomized controlled trial double blind

Protocol summary

Study aim
Effect of topical poppy seed oil on pain relief in patients with severe osteoarthritis of knee

Design
Clinical trial, with case & control group, simple individualy randomised, blind, design on 80 patients, enrolled from Apr 2019 to Jul 2019, which are treatet for 2 weeks and at the first visit and 2, 4, 6 and 8 weeks later, they are evaluated for knee pain.

Settings and conduct
This clinical trial in doing in Imam Ali hospital in Bojnurd. Patients with knee osteoarthritis were divided into two groups receiving poppy seed oil and placebo and are examined at first visit and 2, 4, 6 and 8 weeks later.patients and researcher and analyzer are blind. they are not aware which patient is in which group.

Participants/Inclusion and exclusion criteria
Intrance criteria: Age 45 to 65 years old Severe knee osteoarthritis (based on WOMAC criteria) Idiopathic osteoarthritis Exit criteria: pregnancy Use of tobacoo (drugs, cigarettes, hookahs) or alcohol Lack of skin disease in the knee People with known rheumatic disease People with known gout Sensitivity to diclofenac, asprin and NSAIDS lack of consumption or irregular consumption of oil People who are not physically fit to follow up on the final examination

Intervention groups
In case group:Study of The effect of Poppy seed oil on the knee pain (with the recipe of using: twice aday for 2 weeks and) in patients with osteoarthritis. In control Group: placebo is used in the form of drug and the same intake is similar to poppy seed oil.

Main outcome variables
The amount of knee pain reduction in people who use poppy seed oil The amount of knee pain reduction in people who dont use poppy seed oil

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190429043423N1**
Registration date: **2019-05-01, 1398/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-01, 1398/02/11**
Update count: **0**

Registration date
2019-05-01, 1398/02/11

Registrant information
Name
Tina Alizadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 11 3224 0623
Email address
tina.al1989@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-04-04, 1398/01/15
Expected recruitment end date
2019-06-05, 1398/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Effect of topical poppy oil on pain relief in patients with severe osteoarthritis of knee: randomized controlled trial double blind

Public title
Effect of topical poppy oil on pain relief in patients with severe osteoarthritis of knee
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 45 to 65 years old Severe knee osteoarthritis (based on WOMAC criteria) Idiopathic osteoarthritis
Exclusion criteria:
pregnancy Use of tobacoo (drugs, cigarettes, hookahs) or alcohol Lack of skin disease in the knee People with known rheumatic disease People with known gout Sensitivity to diclofenac, asprin and NSAIDS lack of consumption or irregular consumption of oil People who are not physically fit to follow up on the final examination.
Age
From **45 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with individually randomization unit. the tool used for randomization was Randlist statistical software.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are not aware of taking medicine or plasebo. Researcher & Examiner & Analyzer are not knowing that which patients are in which groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of North Khorasan University of Medical Science
Street address
Central Building of North Khorasan University of Medical Science, Dolat Boulevared, Bojnurd.
City
Bojnurd
Province
North Khorasan
Postal code
74877-94149
Approval date
2019-03-16, 1397/12/25
Ethics committee reference number
IR.NKUMS.REC.1397.111

Health conditions studied

1

Description of health condition studied
Knee pain in patients with knee osteoartheritis
ICD-10 code
M17.10
ICD-10 code description
Unilateral primary osteoarthritis, unspecified knee

Primary outcomes

1

Description
Relaxation of knee pain after using poppy seed oil in patients with knee osteoarthritis
Timepoint
At first visit and then 2, 4, 6 & 8 weeks after starting to use poppy sees oil
Method of measurement
WOMAc & SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Poppy seed oil is used on top of the knee for 2 weeks and twice aday.
Category
Rehabilitation

2

Description
Control group:Plasebo containing base material of Poppy seed oil is used on top of the knee for 2 weeks and twice aday.
Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
imam Ali hospital
Full name of responsible person
Mohsen Abad
Street address
Imam Ali hospital, Payamenour university street, Chamran Ave.
City
Bojnurd
Province
North Khorasan
Postal code
9417694735
Phone
+98 58 3229 7010
Email
M.abad@nkums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bojnourd University of Medical Sciences
Full name of responsible person
سید کاوه حجت
Street address
Central building of north khorasan medical science, dolat boulvar
City
bojnurd
Province
North Khorasan
Postal code
74877-94149
Phone
+98 58 3222 1910
Email
INFO@NKUMS.AC.IR

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Mohsen Abad
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Ali hospital, Payamnoor street, Chamran Ave.
City
Bojnurd
Province
North Khorasan
Postal code
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Phone
+98 58 3229 7010
Email
M.abad@nkums.ac.ir

Person responsible for scientific inquiries

Contact

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Phone
+98 58 3229 7010
Email
M.abad@nkums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Bojnourd University of Medical Sciences
Full name of responsible person
Mohsen Abad
Position
Professer
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Other areas of specialty/work
Anesthesiology
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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