

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 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 individually randomised, blind, design on 80 patients, enrolled from Apr 2019 to Jul 2019, which are treated 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 is being done 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

Inclusion criteria: Age 45 to 65 years old Severe knee osteoarthritis (based on WOMAC criteria) Idiopathic osteoarthritis Exclusion criteria: pregnancy Use of tobacco (drugs, cigarettes, hookahs) or alcohol Lack of skin disease in the knee People with known rheumatic disease People with known gout Sensitivity to diclofenac, aspirin 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 a day 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 don't 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 tobacco (drugs, cigarettes, hookahs) or alcohol Lack of skin disease in the knee People with known rheumatic disease People with known gout Sensitivity to diclofenac, aspirin 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 placebo. 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 osteoarthritis

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.

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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 boultar

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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

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Person responsible for updating data

Contact

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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