

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effectiveness of *Amygdalus communis* var. *amara* oil with placebo, diclofenac and massage in improving joint pain and stiffness and physical function in knee osteoarthritis patients

Protocol summary

Study aim

Comparison of the effectiveness of *Amygdalus communis* var. *amara* oil with placebo, diclofenac and massage in the treatment of knee osteoarthritis patients

Design

Randomized; block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of four patients are used for the treatment assignments. Double-blind; controlled with placebo, diclofenac and massage; four group parallel design; single-center; phase 2 of clinical trial. Study population: patients with knee osteoarthritis. Sample size: 200 patients.

Settings and conduct

The trial setting: Mashhad Emam Reza Hospital. Protocol: 50 patients apply topical bitter almond oil, 50 patients apply topical placebo and 50 patients apply topical diclofenac to the knee every 8 hours for 10 minutes during 1 month and 50 patients only massage the knee without any topical agent application every 8 hours for 10 minutes during 1 month. Before intervention and 1 month after intervention the groups' extent of arthritis, extent of joint pain, extent of joint stiffness and extent of physical function are compared with each other. Blinding: Three different persons generate the random allocation sequence, enroll the participants and assign them to intervention groups. These persons, care providers, outcome assessors, data analyzer, investigators and participants are blinded to assignment to the bitter almond oil, diclofenac and placebo groups. Participants and care providers are not blinded to assignment to the massage group. But, all others are blinded to assignment to the massage group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: male or female patients with 1 or 2 knees osteoarthritis according to the American College of

Rheumatology criteria after physical examination and knee joint radiography; age of 40 to 85 years; flare of the disease after oral non-steroidal anti-inflammatory drug or acetaminophen discontinuation which have been used at least 3 days a week during the past month (flare means increase of at least 2 scores in the total pain subscale score in the beginning of the study); Western Ontario and McMaster Universities (WOMAC) pain subscale index at least 9 out of 20 in the beginning of the study. Exclusion criteria: secondary osteoarthritis (due to a definite disease); arthroscopy; surgery; history of knee replacement surgery; any serious systemic disease (such as concomitant infections, cardiovascular, hepatic and renal diseases); any other chronic inflammatory disease; any history of alcohol, drug and narcotics abuse; skin disease in the knee area; having fibromyalgia and other debilitating diseases affecting the knee; pregnant women; women planning pregnancy; lactating women.

Intervention groups

50 patients apply topical bitter almond oil, 50 patients apply topical placebo and 50 patients apply topical diclofenac to the knee every 8 hours for 10 minutes during 1 month and 50 patients only massage the knee without any topical agent application every 8 hours for 10 minutes during 1 month.

Main outcome variables

Primary outcome variable: extent of arthritis. Secondary outcome variables: extent of joint pain, extent of joint stiffness, extent of physical function.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170821035817N1**

Registration date: **2017-12-17, 1396/09/26**

Registration timing: **prospective**

Last update: **2017-12-17, 1396/09/26**
Update count: **0**
Registration date
2017-12-17, 1396/09/26

Registrant information
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Recruitment status
Recruitment complete
Funding source
Vice Chancellor for Research, Mashhad University of Medical Sciences; Vice Chancellor for Research, ACECR Institute of Medicinal Plants

Expected recruitment start date
2018-04-21, 1397/02/01
Expected recruitment end date
2019-04-21, 1398/02/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of Amygdalus communis var. amara oil with placebo, diclofenac and massage in improving joint pain and stiffness and physical function in knee osteoarthritis patients

Public title
Effect of bitter almond oil in treatment of knee arthrosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Male or female patients with 1 or 2 knees osteoarthritis according to the American College of Rheumatology criteria after physical examination and knee joint radiography Age of 40 to 85 years Flare of the disease after oral non-steroidal anti-inflammatory drug or acetaminophen discontinuation which have been used at least 3 days a week during the past month (flare means increase of at least 2 scores in the total pain subscale score in the beginning of the study.) Western Ontario and McMaster Universities (WOMAC) pain subscale index at least 9 out of 20 in the beginning of the study
Exclusion criteria:
Secondary osteoarthritis (due to a definite disease) Arthroscopy Knee surgery History of knee replacement surgery Infection Cardiovascular disease Hepatic disease Renal disease Other chronic inflammatory disease History of alcohol abuse History of drug abuse History of

narcotic abuse Skin disease in the knee area
Fibromyalgia Debilitating disease affecting the knee
Pregnant women Women planning pregnancy Lactating women

Age
From **40 years** old to **85 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of four patients are used for the treatment assignments.

Blinding (investigator's opinion)
Double blinded

Blinding description
Three different persons generate the random allocation sequence, enroll the participants and assign them to intervention groups. These persons, care providers, outcome assessors, data analyzer, investigators and participants are blinded to assignment to the bitter almond oil, diclofenac and placebo groups. Participants and care providers are not blinded to assignment to the massage group. But, all others are blinded to assignment to the massage group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Building of Mashhad University of Medical Sciences, Shahid Fakuri Boulevard, Danesh Salamat Town
City
Mashhad

Province

Razavi Khorasan

Postal code

99191-91778

Approval date

2017-07-15, 1396/04/24

Ethics committee reference number

IR.MUMS.REC.1396.142

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

Osteoarthritis

ICD-10 code

M19.9

ICD-10 code description

Arthrosis, unspecified

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

Extent of arthritis

Timepoint

Before intervention and 1 month after intervention

Method of measurement

The Western Ontario and McMaster Universities Arthritis

Index questionnaire

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

Extent of joint stiffness

Timepoint

Before intervention and 1 month after intervention

Method of measurement

The Western Ontario and McMaster Universities Arthritis

Index questionnaire

2**Description**

Extent of joint pain

Timepoint

Before intervention and 1 month after intervention

Method of measurement

The Western Ontario and McMaster Universities Arthritis

Index questionnaire

3**Description**

Extent of physical function

Timepoint

Before intervention and 1 month after intervention

Method of measurement

The Western Ontario and McMaster Universities Arthritis

Index questionnaire

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

Fifty patients apply topical bitter almond oil to the knee every 8 hours for 10 minutes during 1 month

Category

Treatment - Drugs

2**Description**

Fifty patients apply topical diclofenac to the knee every 8 hours for 10 minutes during 1 month

Category

Treatment - Drugs

3**Description**

Fifty patients massage the knee without application of any topical agent every 8 hours for 10 minutes during 1 month

Category

Treatment - Other

4**Description**

Fifty patients apply topical placebo to the knee every 8 hours for 10 minutes during 1 month

Category

Placebo

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

Emam Reza hospital

Full name of responsible person

Ali Khorsand Vakilzadeh

Street address

Emam Reza hospital, Daneshgah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Dr. Reza Hajiaghaee

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

Yes

Title of funding source

Iranian academic center for education culture and research

Proportion provided by this source

50

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

ACECR Institute of Medicinal Plants

Full name of responsible person

Dr. Saeed Kianbakht

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Pharmacology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Ali Khorsand Vakilzadeh

Position

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Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Dr. Maryam Yaghoubi

Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All collected deidentified IPD are to be shared.

When the data will become available and for how long

Access period starting 6 months after publication for 1 year

To whom data/document is available

Researchers working in university and scientific and industrial institutes

Under which criteria data/document could be used

Only statistical analyses mentioned in the article resulting from the study for personal knowledge are permitted. Written request for access to data and documents and its aim must be certified by the highest ranking official of the work place of the requester.

From where data/document is obtainable

Dr. Saeed Kianbakht with the address ACECR Institute of Medicinal plants, P.O. Box: 31375-369, Iran

What processes are involved for a request to access data/document

Written request should be sent to the address Dr. Saeed Kianbakht, ACECR Institute of Medicinal Plants, P.O. Box: 31375-369, Iran. The documents or data file will be sent to the requester by email.

Comments