

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Formulation of traditional preparation of “shevid marham” and a novel topical drug delivery form the essential oil a of Dill (Anethum graveolens) and study of their effect on pain in osteoarthritis of knee.

Protocol summary

Study aim

Formulation of traditional preparation of “shevid marham” and a novel topical drug delivery form the essential oil a of Dill (Anethum graveolens) and study of their effect on pain in osteoarthritis of knee.

Design

According to similar studies, 90 patients were randomly assigned to receive the drug and placebo. And receive the drug with the code.

Settings and conduct

The research area is Pasteur Bam Hospital. After completing three to four weeks (once daily twice and once per gram), the relevant questionnaires (VAS, WOMAC) are completed.

Participants/Inclusion and exclusion criteria

1. Primary knee osteoarthritis patients aged 40 to 80 years 2. Joint pain of osteoarthritis with or without symptoms 3. Significant radiological symptoms of knee osteoarthritis 4. Qualify for patients with knee osteoarthritis according to American Rheumatology Association criteria Exit criteria: 1. Patients with acute phase of knee arthritis 2. Having secondary osteoarthritis (such as severe joint trauma and mathologic diseases) 3. Failure to track enough 4. Diabetic neuropathy

Intervention groups

. Traditional form recipient • Recipient of sesame oil (placebo) • New form recipient • Recipient of all new formulations without active substance (placebo) • Recipient of diclofenac ointment (positive control)

Main outcome variables

Intensity of pain The amount of pain in different situations Percentage of active ingredients in the formulation Duration of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170702034861N7**

Registration date: **2019-02-27, 1397/12/08**

Registration timing: **registered_while_recruiting**

Last update: **2019-02-27, 1397/12/08**

Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Fariba Sharififar

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 34 3132 5020

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Recruitment status

Recruitment complete

Funding source

Research project

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation of traditional preparation of “shevid marham” and a novel topical drug delivery form the essential oil of Dill (*Anethum graveolens*) and study of their effect on pain in osteoarthritis of knee.

Public title

The effect of *Anethum graveolens* on pain relief from arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Primary knee osteoarthritis patients aged 40 to 80 Joint pain of osteoarthritis with or without symptoms Radiological Signs of Knee Arthritis Patients of Knee Osteoarthritis according to American Rheumatology Association criteria

Exclusion criteria:

Patients with acute phase of knee arthritis Secondary osteoarthritis (such as severe joint trauma and rheumatologic diseases) Inability to keep track of enough Diabetic neuropathy

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, randomly assigned to intervention and control groups. This method uses simple randomization models, such as using random numbers tables or using computer randomization methods, and places each referer, for example, by dropping a coin, into an intervention or control group. The implementation of this method is very simple. The disadvantages of this method are that the sample size of a group may be more than the other. One type of intervention may be given at the beginning of the study and a type of intervention at the end of the study

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and main investigators have been blinded. Patient safety is a priority, so the physician should be informed about the patient's treatment. After randomization of the patients in the intervention and control groups, the drug and placebo with the same appearance will administer to the patient who is blind to the type of medicine. The original researcher is also completely blind to the drug. Medication and placebo are provided to the physician and provided to the patient by him or her. Analysis of the results will be done by a

statistics who is not necessarily the original researcher.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of kerman university of medical sciences

Street address

Ibn Sina St, Tahmasebabad Crossroads

City

Kerman

Province

Kerman

Postal code

7619813159

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.KMU.REC.1397.462

Health conditions studied

1

Description of health condition studied

Osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

pain

Timepoint

14 day

Method of measurement

The Western Ontario and McMaster Universities Osteoarthritis Index

Secondary outcomes

1

Description

Percentage of active ingredients

Timepoint
Once
Method of measurement
GC-MASS

+98 34 4421 4611
Email
Setareh5307@gmail.com

Intervention groups

1

Description
Make up to one gram twice a day, topically
Category
Treatment - Drugs

2

Description
novel formulation of extracts and essential oils in a dose of 1 gram twice a day
Category
Treatment - Drugs

3

Description
Sesame oil is 1 g twice a day
Category
Placebo

4

Description
novel formulation except active ingredient One gram twice a day
Category
Placebo

5

Description
diclofenac ointment One gram twice a day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Pastor hospital
Full name of responsible person
Mazyar Oveisi
Street address
No. 10,Imam Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fariba Sharififar
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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
Kerman 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
Kerman University of Medical Science
Full name of responsible person
Setareh Saei
Position
Traditional Pharmaceutical Assistant
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Person responsible for updating data

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

data of unidentifiable of participants

When the data will become available and for how long

After complete data analysis and presentation of final report

To whom data/document is available

due to publication of data, there is no limitation

Under which criteria data/document could be used

There are no limitations.

From where data/document is obtainable

with main researcher

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

communication through e- mail and response receiving

Comments

No comment.