Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 osteoarthiritis 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 osteoarthiritis 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
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Name of organization / entity
Kerman University of Medical Sciences

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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 a of Dill (Anethum graveolens) and study of their effect on pain in osteoarthiritis 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 rhomathologic 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
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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

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
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Sponsors / Funding sources

1

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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
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Setareh Saei
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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 unidentifiabe 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 recieving
Comments
No comment.