Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Efficacy of semi-solid form of extract of chamomile, Thymus vulgaris L and Oliveria decumbens to relieve osteoarthritis pain in patients with osteoarthritis.

Protocol summary

Study aim

The effect of cream and gel prepared from the extract of Thyme, Chamomile and Oliveria decumbens on osteoarthritis pain relief.

Design

Phase 3 clinical trial, consisting of two drug-using groups (cream and gel) and one placebo-treated group, with parallel groups, one-blind, randomized block design with a sample size of 100, one-step sampling, non-probability and easy.

Settings and conduct

The study is performed in a rheumatologist's office and under the supervision of a physician. Upon presentation, the patient is given a questionnaire that should be administered for 3 weeks and filled in each week. The physician and the patient are completely blind and only the researcher is aware of the medication the patient is giving.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with osteoarthritis have stage 1 and 2 disease. Patient satisfaction to participate in the study. Exclusion criteria:Other underlying diseases that interfere with the study of the effect of the drug. Pregnant women and lactating women. Addicts (natural opiates, synthetics or alcohol).

Intervention groups

This study consists of 3 groups. The first group used the cream and the second group as the control group and the third group as the placebo control group to evaluate the effect of the drug on osteoarthritis pain. After the patient is selected by the physician and explained to them, we proceed to distribute the drug.

Main outcome variables

Pain severity; Weakness in daily life function; Knee stiffness.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130722014106N7**
Registration date: **2019-12-24, 1398/10/03**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-24, 1398/10/03**
Update count: **0**

Registration date

2019-12-24, 1398/10/03

Registrant information

Name

Reza Tahvilian

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 83 1427 6482

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-01, 1398/09/10

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of semi-solid form of extract of chamomile, Thymus vulgaris L and Oliveria decumbens to relieve osteoarthritis pain in patients with osteoarthritis.

Public title
Effect of semi-solid form ofextract of chamomile, Thymus vulgaris L and Oliveria decumbens on osteoarthritis pain.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with osteoarthritis have stage 1 and 2 disease.. Patient satisfaction to participate in the study.

Exclusion criteria:
Other underlying diseases that interfere with the study of the effect of the drug. Pregnant women and lactating women. Addicts (natural opiates, synthetics or alcohol).

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization will be determined online using the sealedenvelope.com site, blocks and allocation modes. This is based on a sample size of 102 patients with 3 treatment groups (group I cream (A), group II gel (B) and group III, placebo (C)), the blocks are considered to be 6 (6 persons per block), with a total of 17 blocks of 6 persons. For example a few blocks below. Patients in this study would not be aware of medication or placebo. Block 1: BACABC Block 2: AABCCB Block 3: CCABAB And ...

Blinding (investigator's opinion)
Single blinded

Blinding description
To blind the study, the drugs and placebo were designed to be exactly similar in color, odor and concentration, and the physician and the patient could not discern whether patients were taking the drug or the placebo; And only the researcher and the data collector are aware that the patient has used the drug or the placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Research in Kermanshah University of Medical Sciences

Street address
School of Pharmacy, Nursing Blvd., University Ave., Shahid Shiroudi Blvd., Kermanshah

City
Kermanshah

Province
Kermanshah

Postal code
6714415153

Approval date
2019-09-17, 1398/06/26

Ethics committee reference number
IR.KUMS.REC.1398.682

Health conditions studied

1

Description of health condition studied
Osteoarthritis Pains

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Evaluation of the effect of medication on osteoarthritis pain by the score of completing a questionnaire delivered to the patient.

Timepoint
Symptoms of pain relief are at 7, 14 and 21 days after starting medication.

Method of measurement
How to measure the efficacy of the drug is determined by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) questionnaire completed by the patient.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group I : This group of patients with osteoarthritis pain, uses cream containing 15% of 3 plant extracts blend in cream base. The patient should use the cream 3 times a day for 3 weeks and complete the questionnaire each week.
Category
Treatment - Drugs

2

Description
Intervention group II: This group of patients with osteoarthritis pain, uses gel. Includes: 3 Plant Extracts Blend 15% in gel base. The patient should take the drug 3 times a day for 3 weeks and complete the questionnaire each week.
Category
Treatment - Drugs

3

Description
Control group: This group of patients with osteoarthritis pain, uses placebo cream and gel, which contains all the ingredients of cream and gel, except for the mixture of 3 plant extracts blend. The patient should take the drug 3 times a day for 3 weeks and complete the questionnaire each week.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdie Clinic
Full name of responsible person
Dr.Mehran Pour Nazari
Street address
Mahdie Clinic, opposite Shirin Park, Javanshir Blvd., Kermanshah
City
Kermanshah
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Kermanshah
Postal code
6715847141
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+98 83 3727 7700
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rtahvilian@kums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Vice chancellor for research and technology, Building 2, Shahid Beheshti Blvd
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Postal code
6715847141
Phone
+98 83 3838 4185
Email
farid_n32@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Reza Tahvilian
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Associate Professor

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Other areas of specialty/work
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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
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

Title and more details about the data/document
All data can be shared in the form of scores from patient completed questionnaires.

When the data will become available and for how long
6 months after printing the results.

To whom data/document is available
Researchers working in academic institutions.

Under which criteria data/document could be used
They are only allowed to study the data and use it as a source.

From where data/document is obtainable
Kermanshah University of Medical Sciences Sayyed Milad Mousavi Mehr miladmosavi8977@gmail.com

What processes are involved for a request to access data/document
Once they have sent the email and registered the request, they will be sent.

Comments