# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
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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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**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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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
Dr. Reza Tahvilian

**Position**
Associate Professor

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**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**
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**