Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Clinical effects of a herbal formulation in relieving inflammation and joint pains in patients with osteoarthritis

Protocol summary

Study aim
Investigating the clinical effects of a herbal formulation in relieving inflammation and joint pains in patients with osteoarthritis

Design
In this study, 60 patients with osteoarthritis that referred to the Imam Reza clinic will be selected based on the inclusion criteria and randomly divided into intervention and control groups. Each participant will be assigned a unique code.

Settings and conduct
This study, which will be carried out at the Imam Reza clinic in Kermanshah city, is double blinded and investigators and patients will be kept blinded to taking medication or placebo. At the beginning of the study, pain and joints stiffness in both groups will be recorded in a checklist

Participants/Inclusion and exclusion criteria
Inclusion criteria : Over 50 years old; No change in medication and treatment regimen in the last three months. Exclusion criteria: Pregnant women; women who intend to be pregnant; and lactating women; Addicted people (natural, synthetic or alcoholic drugs)

Intervention groups
The intervention group will receive the herbal medicine every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month. The control group, will receive the placebo every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month.

Main outcome variables
Joint pain; joints stiffness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131219015870N2**
Registration date: **2018-01-07, 1396/10/17**
Registration timing: **prospective**

Last update: **2018-01-07, 1396/10/17**
Update count: **0**

Registration date
2018-01-07, 1396/10/17

Registrant information

Name
Amir Kiani

Name of organization / entity
Kermanshah University of Medical Science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
kermanshah University of Medical Sciences(KUMS)

Expected recruitment start date
2018-01-10, 1396/10/20

Expected recruitment end date
2018-06-10, 1397/03/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical effects of a herbal formulation in relieving inflammation and joint pains in patients with osteoarthritis

Public title
Clinical effects of a herbal formulation in relieving inflammation and joint pains
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Average age over 50 years During the last three months, the type and regimen of the medication and treatment used for the patient have not changed. Patients who have injected hyaluronic acid
Exclusion criteria:
Patients who have other diseases or use other medications Pregnant women, women who intend to have a pregnancy and breast-feeding women Addicted people (natural, synthetic or alcoholic drugs) Patients who will get another illness during treatment or be forced to use another drug
Age
From **50 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done using random number table.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the investigator and patients will be kept blind to taking medication or placebo
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Approval date
2016-11-23, 1395/09/03
Ethics committee reference number
KUMS.REC.1395.505

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
joint pain
Timepoint
At the beginning of the study and the end of the study (one month later)
Method of measurement
Using the The Western Ontario and McMaster Universities Osteoarthritis questionnaire (WOMAC)

2

Description
Dryness of the joint
Timepoint
At the beginning of the study and the end of the study (one month later)
Method of measurement
Using the The Western Ontario and McMaster Universities Osteoarthritis questionnaire (WOMAC)

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group will receive the herbal medicine every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month
Category
Treatment - Drugs

2

Description
The control group, will receive the placebo every night in the form of a topical cream in an approximate amount of two grams by rub on knee joint for one month.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
KUMS
Full name of responsible person
Amir kiani
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Emam Reza Hospital, Parastar Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Farid Najafi
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
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6715847141
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+98 83 3836 0014
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fnajafi@kums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Kermanshah University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
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
Elham Choolaki
Position
Medicine student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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Medicine student

Latest degree

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

The main outcomes of the study will be shared.

When the data will become available and for how long

6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

En Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

En In a 15-day period, the documents will be sent e-mail

Comments