

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Treatment of osteoarthritis of the knee with a topical doxepin: A randomised controlled trial

Protocol summary

Study aim

Evaluation of Analgesic Effects of Doxepin Cream in patients with knee osteoarthritis

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 on 60 patients. Random allocation concealment was used for randomization.

Settings and conduct

This study is a double-blind, placebo-controlled, single-center clinical trial in which Randomization concealment was performed on 60 patients with osteoarthritis referred to Rasool Akram orthopedic clinic. Patients with osteoarthritis are divided into three groups of 20 people. The first group uses placebo cream 3 times a day, the second group uses 5% topical Doxepin cream 3 times a day and the third group uses 1% diclofenac topical gel 3 times a day. All three groups take 250-500 mg of naproxen tablets orally daily. The Western Ontario and McMaster (WOMAC) and Visual Analogue Scale (VAS) questionnaires are checked at the beginning of the study and six weeks after the start of treatment. Improving physical function and reducing pain is the answer to treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 45_75 years old; a definitive diagnosis of osteoarthritis disease with specialist Exclusion criteria: severe diseases such as metabolic disorders and digestive at the same time; severe infection, sensitivity to thyme extract daenensis, pregnancy, lactation, impaired liver function tests; history of fracture or knee surgery; rheumatoid arthritis

Intervention groups

Patients with osteoarthritis are divided into three groups of 20 people. The first group uses placebo cream twice a day, the second group consumes 5% doxepin cream 2 times a day for half a fingertip, and the third group consumes 1% diclofenac topical gel the same amount as doxepin group 2 times a day. All three groups take

250-500 mg of naproxen tablets orally daily.

Main outcome variables

Improving physical Function; Pain relief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161204031229N7**

Registration date: **2022-04-14, 1401/01/25**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-14, 1401/01/25**

Update count: **0**

Registration date

2022-04-14, 1401/01/25

Registrant information

Name

Azadeh Eshraghi

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy-International Campus, Iran University of Medica

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-14, 1401/01/25

Expected recruitment end date

2022-06-07, 1401/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Treatment of osteoarthritis of the knee with a topical doxepin: A randomised controlled trial

Public title

Doxepin cream in reducing knee pain due to Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

45_75 years old A definitive diagnosis of osteoarthritis disease with specialist

Exclusion criteria:

Severe diseases such as metabolic disorders and digestive at the same time Severe infection Sensitivity to Doxepin cream Pregnancy Lactation Impaired liver function tests History of fracture or knee surgery Rheumatoid arthritis

Age

From **45 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the simple randomization method will be used. The randomization sequence will be determined by the researchers first and then we will proceed to sampling. In this way, we will have 2 pots, in pot number 1 will be numbers from 1 to 63, and in pot number 2, 63, the number of envelopes will be opaque, in which the desired type of treatment is listed. First we will randomly select a number from the first pot and from the second pot we will randomly select an envelope and place them in a designed box. The number from pot number 1 will receive the treatment that came out of pot number 2. We will do this for every 63 issues. In fact, the type of intervention inside each envelope is unclear, which is the randomization concealment method. In fact, the treatment assigned to the numbers is not known until the person comes and the envelope is opened for him, and secondly, the names of the treatments will not be known inside the envelopes, and the names of the treatments will be A, B and C, and only the designer The study will know the type of treatment A and B, C.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient and the interventionist or physician are blind and the drug group and placebo are used for blinding. After selecting the samples, the patient and the intervener or physician will have no information about randomization and the allocation process. Physicians are pre-coded (A, B, C) and patients are admitted to the study, respectively.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of Medical Sciences

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Hemmat Highway

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Tehran

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Postal code

1449614535

Approval date

2022-03-16, 1400/12/25

Ethics committee reference number

IR.IUMS.REC.1400.1247

Health conditions studied**1****Description of health condition studied**

Knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes**1****Description**

Improving physical Function

Timepoint

Baseline and Six Weeks later

Method of measurement

Western Ontario and McMaster (WOMAC) questionnaire

2

Description

Pain relief

Timepoint

Baseline and Six Weeks later

Method of measurement

Visual Analogue Scale (VAS) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

'Control group:" The first group received placebo cream Khoramabad University of Medical Sciences, topically 3 times a day with 250-500 mg naproxen capsules for oral use

Category

Placebo

2

Description

"Intervention group 1:" The Second group received Doxepin 5% Khoramabad University of Medical Sciences, topically 3 times a day with 250-500 mg naproxen capsules for oral use

Category

Treatment - Drugs

3

Description

"Intervention group 2:" The Third group received diclofenac 1% gel Nazho topically 3 times a day with 250-500 mg naproxen capsules for oral use

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasool Akram Hospital

Full name of responsible person

Azadeh Eshraghi

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Niayesh street, Satarkhan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Azadeh Eshraghi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available