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 concealmen 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

Country
Iran (Islamic Republic of)

Phone
+98 86709

Email address
eshraghi.a@iums.ac.ir

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
Street address
Hemmat Highway
City
Tehran
Province
Tehran
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 Rasoole Akram Hospital
Full name of responsible person
Azadeh Eshraghi
Street address
Niayesh street, Satarkhan street
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2504
Email
aepharm@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mahdi Rezai
Street address
Emergency Medicini Managemet Research Center, Vanak Square, Tehran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 8819 1706
Email
mah_re@yahoo.com
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
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran

Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2030
Email
eshraghi.a@iums.ac.ir

Person responsible for scientific 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
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2030
Email
eshraghi.a@iums.ac.ir

Person responsible for updating data

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
Street address
Iran University of Medical Sciences, Hemmat Highway, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
009821867020930
Email
eshraghi.a@iums.ac.ir

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