Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluating the effect of topical pregabalin 2% compared to with diclofenac 1% in patients with knee osteoarthritis: a double-blind randomized clinical trial

Protocol summary

Study aim
Determining the effect of topical pregabalin 2% in comparison with diclofenac 1% in patients with knee osteoarthritis

Design
Control-controlled clinical trial with parallel, double-blind, randomized, phase 3 groups on 93 patients used the Excel software rand function for randomization.

Settings and conduct
This project was carried out at Shahid Sadoughi Hospital in Yazd. Patients in three groups of 31 people use pregabalin 2% topical cream, diclofenac gel and placebo cream 3 times a day for 4 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients aged 45 to 75 years with knee osteoarthritis who have a pain score higher than 4. Exclusion criteria: other joint diseases Allergy to NSAID or pregabalin Severe osteoarthritis that requires surgery Taking oral pregabalin or duloxetine Taking narcotic painkillers

Intervention groups
In order to investigate the effectiveness of topical pregabalin in knee osteoarthritis, we will give a group of 31 people 2% topical pregabalin (manufactured in the Yazd Faculty of Pharmacy), a group of 31 people 1% topical diclofenac gel, and a group of 31 people a placebo cream (manufactured in the Yazd Pharmacy Faculty).

Main outcome variables
Severity of patient pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181208041882N12**
Registration date: **2023-10-14, 1402/07/22**
Registration timing: **retrospective**

Last update: **2023-10-14, 1402/07/22**
Update count: **0**

Registration date
2023-10-14, 1402/07/22

Registrant information

Name
behrooz heydari

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3820 8699

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b.heydari@ssu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-22, 1397/03/01

Expected recruitment end date
2023-04-20, 1402/01/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of topical pregabalin 2% compared to with diclofenac 1% in patients with knee osteoarthritis: a double-blind randomized clinical trial

Public title

Topical pregabalin in the treatment of osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 45 to 75 years Pain score more than 4 Diagnosis of knee osteoarthritis based on the criteria of the American College of Rheumatology (ACR)

Exclusion criteria:

Other joint diseases Hypersensitivity to NSAID or pregabalin Severe osteoarthritis that requires surgery Taking oral pregabalin or duloxetine Taking narcotic painkillers

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 93 patients were randomly divided into two treatment groups (A, B, C). In order to randomize, the block random allocation method was used, in which 10 blocks of 10 were considered. The letters A, B A and C. These permutations were generated with the help of Random software distribution software version 1. For this purpose, the list prepared by software No. 1 to 93 is in 10 blocks of ten in general to implement this I want the software output to the first eligible person number 1 and I want to select the last person number 93.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients, the clinical caregiver and the outcome assessor were not aware of the type of medication the patients received.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine- Shahid Sadoughi University of Medical Sciences

Street address

Shahid Sadoughi University of Medical Science, Shohadaye Gomnam Blvd, Alem Sq

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2018-05-16, 1397/02/26

Ethics committee reference number

IR.SSU.MEDICINE.REC.1397.042

Health conditions studied

1

Description of health condition studied

Osteoarthritis of knee

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Improvement of osteoarthritis symptoms

Timepoint

The start of treatment and the fourth week

Method of measurement

Mac Master Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients with knee osteoarthritis use pregabalin 2% topical cream (made in Yazd Faculty of Pharmacy) topically 3 times a day and 1 gram each time for 4 weeks.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients with knee osteoarthritis

use 1% diclofenac topical gel topically 3 times a day and 1 gram each time for 4 weeks.

Category
Treatment - Drugs

3

Description
Control group: Patients with knee osteoarthritis use placebo cream topically 3 times a day and 1 gram each time for 4 weeks.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Sadoughi hospital

Full name of responsible person
Hossien Soleymani Salehabadi

Street address
Ibn Sina Street, Shahid Ghandi Boulevard, Safaieh, Yazd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Amin Salehi Abarghouei

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Grant name

Grant code / Reference number

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

Title of funding source
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Behrooz Heydari

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)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Title and more details about the data/document
After nonrecognition, all data can be share
When the data will become available and for how long
6 months after publication
To whom data/document is available
All of researchers
Under which criteria data/document could be used
Nothing
From where data/document is obtainable
Behrooz Heydari email: b.heydari@ssu.ac.ir
What processes are involved for a request to access data/document
Request your information by email. The data will be sent after a week.
Comments