

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of therapeutic effects of topical ketorolac versus topical diclofenac in the treatment of knee osteoarthritis pain: a clinical trial

Protocol summary

Study aim

Making Ketorolac Cream and Comparing the Therapeutic Effects of Topical Diclofenac Ketorolac in Relieving Knee Osteoarthritis Pain

Design

randomized, parallel-group, double-blind, placebo-controlled phase 2 clinical trial on 60 patients (two groups of 30).

Settings and conduct

Shahid Sadoughi Hospital, Yazd, The effect of ketorolac in comparison with diclofenac on osteoarthritis of the knee, double-blind clinical trial (orthopedic physician and patient, none of the grouping will be known. The patient will be randomly divided into 2 groups receiving topical ketorolac, or topical diclofenac randomly divided into permutation blocks (30 in each group). And 3 times a day, they use its topical form for 2 weeks. Patients did not use other therapies such as exercise and physiotherapy during the 2 weeks of the study and will not change their treatment regimen during this period.

Participants/Inclusion and exclusion criteria

Patients over 40 years of age with primary tibiofemoral or patellofemoral osteoarthritis with baseline WOMAC scale

Intervention groups

Control group: topical diclofenac 1% three times a day for two weeks Intervention group: topical ketorolac three times a day for two weeks If the pain is not controlled with each of the topical products, the patient can use acetaminophen tablets in the form of 500 mg up to 4 grams per day. The number of tablets is recorded by the patient and recorded in the visits by the student.

Main outcome variables

Joint range of motion, swelling rate, amount and severity of pain, joint dryness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N22**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **prospective**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Fatemeh Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3820 3419

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effects of topical ketorolac versus topical diclofenac in the treatment of knee osteoarthritis pain: a clinical trial

Public title

The effect of topical ketorolac on knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 40 Primary osteoarthritis Pain in more than half of the days of the previous month during one of the following activities: walking, going up and down stairs, standing or lying on a bed or mattress during Night Radiographic evidence of tibiofemoral or patellofemoral osteoarthritis baseline score of 40 on the WOMAC scale no intra-articular injection of hyaluronic acid / glucocorticoid during the last six months no positive pregnancy test or pregnancy program during the study

Exclusion criteria:

Not taking the right medicine Serious medical condition in which the patient is unable to return for regular visits History of liver disease Inability to walk without a cane Secondary osteoarthritis for example following trauma

Age

From **40 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly assigned to two groups of 20 controls or interventions by the permutation block method. Ten blocks of 4 are considered. Generation of random codes using Permuted Block Randomization method will be done with the help of Random allocation software (version 1). The first person who is eligible to enter the study is given number one and likewise, the last eligible person is given number 40. By using the software-generated table, patients receive each intervention A or B (Each of the letters A and B will be installed on similar containers of the interventions). In order to consider blinding in random allocation, the list is given to another person outside the study and using short message service (SMS) before assigning the type of treatment according to the number of eligible people is asked and thus people enter the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

After the products have been prepared, the first Executor, the treating physician, and the researcher monitoring the patients will not be aware of any of the groupings performed. In this way, after preparing the products, which all look the same, are placed in similar boxes. Then we ask another person to identify them with

the codes A or B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Medical School - Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Anonymous Martyrs Boulevard - Shahid Sadoughi University of Medical Sciences, Yazd

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Postal code

8915173143

Approval date

2022-01-12, 1400/10/22

Ethics committee reference number

IR.SSU.MEDICINE.REC.1400.367

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**

Joint range of motion

Timepoint

At the beginning of the study and 7 and 14 days after starting topical ketorolac and topical diclofenac

Method of measurement

Western ontario and mc master universities osteoarthritis index and Knee Injury and Osteoarthritis Outcome Score

Secondary outcomes

1

Description

pain

Timepoint

At the beginning of the study and 7 and 14 days after starting ketorolac topical and diclofenac

Method of measurement

Western Ontario and mc master universities osteoarthritis index and Visual Analogue Scale and Knee Injury and Osteoarthritis Outcome Score

2

Description

inflammation

Timepoint

At the beginning of the study and 7 and 14 days after starting ketorolac topical and diclofenac

Method of measurement

Western ontario and mc master universities osteoarthritis index and Visual Analogue Scale and Knee Injury and Osteoarthritis Outcome Score

Intervention groups

1

Description

Intervention group: Patients will use the topical gel of ketorolac 2% (prepared in the Pharmaceuticals Laboratory of Yazd School of Pharmacy) three times daily for 2 weeks. Patients will be evaluated for joint function, pain, and inflammation in the first and second weeks. Acetaminophen 500 mg tablets (Jalinus) will also be prescribed in patients' prescriptions so that if the pain is not controlled with these topical products, the patient will use a maximum of four acetaminophen 500 mg daily, provided that all acetaminophen blisters are used during this period. Has been kept until the end of 14 days. During treatment, patients will be monitored for side effects. For patients, a health assessment questionnaire, WOMAC pain assessment questionnaire, and VAS questionnaire will be evaluated for side effects.

Category

Treatment - Drugs

2

Description

Control group: Patients use the topical gel of diclofenac 1% (Iran Najo) three times daily for 2 weeks. Patients will be evaluated for joint function, pain, and inflammation in the first and second weeks. Acetaminophen 500 mg tablets (Jalinus) will also be prescribed in patients' prescriptions so that if the pain is not controlled with these topical products, the patient will use a maximum of four acetaminophen 500 mg daily, provided that all acetaminophen blisters are used during this period. Has been kept until the end of 14 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital, Yazd

Full name of responsible person

Dr. Mohammad Reza Bashiri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

amirhushang mehrparvar

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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

mehdi rostami

Position

university student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

Fatemeh Saghafi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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