Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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
City
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Province
Yazd
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 Pharmaceutics 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
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
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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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دانشجو

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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