Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Analgesic efficacy of diclofenac and ketoprofen transdermal patches versus ibuprofen oral tablets on pain control after initial arch wire placement in orthodontic patients -a randomized clinical trial study

Protocol summary

Study aim

Analgesic efficacy of diclofenac and ketoprofen transdermal patches versus ibuprofen oral tablets on pain control after initial arch wire placement in orthodontic patients

Design

A randomized, double-blind, parallel group, controlled clinical trial. 48 patients will divided in 3 groups by stratified permuted blocks method.

Settings and conduct

This study will be done in the orthodontic department of Guilan Dental School. patients will be randomly placed in 3 parallel groups based on preset blocks. first orthodontic appliances will be placed in both jaws. In the ketoprofen and diclofenac group, patients will be asked to apply the patch immediately after placing the archwire, 8 hours later and the next morning. In the ibuprofen group, people will use the pill immediately after placing the archwire, 8, 16 and 24 hours later. The intensity of pain will measure by using the Numeric Rating Scale form. The therapist, researcher and data evaluators are blinded, but the patients are not blinded due to the different nature of the drugs.

Participants/Inclusion and exclusion criteria

Patients who are in the age range of 18 and 30 years old and according to the classification of the American Society of Anesthesiology, are in the ASA I group, will be included. Patients should have 3-6 mm of crowding in both jaws and should not taking any painkillers at the moment. Also, the patient should not report a history of gastrointestinal discomfort or any allergy to aspirin-like drugs such as ibuprofen.

Intervention groups

48 patients will divided into 3 groups.16 patients will use 30 mg ketoprofen patch, 16 patients will use 1.3% diclofenac epolamine patch and 16 patients will use 400 mg ibuprofen tablet after initial wire placement.

Main outcome variables

The pain intensity of the patients immediately after the treatment and 2, 6 hours, while sleeping, 24, 48 hours, 3 and 7 days after the treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190915044771N2**
Registration date: **2024-03-04, 1402/12/14**
Registration timing: **prospective**

Last update: **2024-03-04, 1402/12/14**
Update count: **0**

Registration date

2024-03-04, 1402/12/14

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2024-07-05, 1403/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Analgesic efficacy of diclofenac and ketoprofen transdermal patches versus ibuprofen oral tablets on pain control after initial arch wire placement in orthodontic patients -a randomized clinical trial study

Public title

Analgesic efficacy of transdermal patches versus oral tablets on pain control of orthodontic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who want to start fixed orthodontic treatment of 2 jaws. Patients should be in the age range of 18 to 30 years. Patients should be healthy in terms of physical condition, without any systemic disease and according to the classification of the American Society of Anesthesiology should be in ASA I group. Based on Little's Irregularity Index, patients should have 3-6 mm of crowding in both upper and lower jaws and do not need tooth extraction. Patients should not take any medication at the moment. Patients should not report a history of bleeding or gastrointestinal discomfort or any allergies after taking Asprin-like drugs such as ibuprofen, and should not have any problems using ketoprofen, diclofenac, and ibuprofen.

Exclusion criteria:

Patients who have taken any painkiller within 24 hours before treatment. Patients who cannot give informed consent. Patients who are illiterate. Patients who need restoration, root canal treatment or extraction of their teeth. Patients who have spontaneous pain in their teeth or periodontal problems do not allow to start orthodontic treatment. Patients who are pregnant or breastfeeding their babies. Patients who have a history of liver or kidney diseases or take drugs that affect these 2 organs.

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

4

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: block Unit of randomization: stratified Randomization strata: sex, drug How the random sequence was built: permutation Allocation concealment: all the drugs will be packed in same unclear sealed envelops which is not distinguishable for the researcher. This process will be done by a third person that is unaware of the object and protocol of the study. complete explanation of Randomization: Based on Stratified Permuted Blocks, all the patients who agreed to participate in the research will be randomly assigned a drug envelope that contains the studied drugs and their usage method. This operation will be performed by the therapist's assistant. Since 48 patients will enter the randomization process and the variables of gender and type of drug are considered as criteria for classification, the patients will divided into 3 groups of 16 (8 males and 8 females). A, B, C will be labeled on the envelopes. 48 envelopes will divided into two groups, blue and red. If the client is a woman, the red envelope will pickup, and if the client is a man, the blue envelope will be prescribed. The envelopes will be filled with drugs and how to use them according to the order of the following three-number blocks based on the sequence of simple randomization. Blue envelopes: ABC, ACB, BAC, BCA, CBA, CAB, ABC, ACB Red envelopes: CAB, CBA, ABC, ACB, BAC, BCA, ABC, ACB In order to hide the random allocation, the method of Sequentially numbered, sealed opaque envelopes which is abbreviated as SNOSE will be used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients do not become blind due to the prescription of different drugs; But since they do not meet each other, they will not understand the difference of prescription drugs. In this study, the therapist (orthodontist), researcher and statistical analyst will not be aware of randomization and the drugs prescribed for the patients. Only the therapist's assistant (allocating samples to groups) is aware of the prescription drug by coding the drug packages and registering them. Patients will communicate only with the therapist's assistant, they will send him their pain level form after taking the drugs and ask him any questions.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Guilan university of medical sciences

Street address

No. 20, Faraz building, Fajr Alley, Namjoo Ave

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Rasht
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Postal code
4144693358
Approval date
2024-01-31, 1402/11/11
Ethics committee reference number
IR.GUMS.REC.1402.577

Health conditions studied

1

Description of health condition studied
pain after initial arch wire placement in orthodontic patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain intensity after initial arch wire placement in orthodontic patients
Timepoint
Immediately after arch wire placement and 2, 6 hours later, while sleeping, 24, 48 hours, 3 and 7 days after treatment
Method of measurement
Numerical rating scale (NRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Name of the drug: Ketoprofen, How to use: Skin patch (patches with the trademark Kefentech from jeil health science company), Patch concentration: 30 mg, Frequency:3 times every 12 hours, Duration: 24 hours. Additional Description: Patch Placement: Hairless areas on the arm or forearm
Category
Treatment - Drugs

2

Description
Intervention group2: Name of the drug: Diclofenac, How to use: Skin patch (patches with the trademark Flector EP tissugel from Altergon Italia Srl company), Patch concentration: 1.3 percent Diclofenac epolamine(including 1%diclofenac equal to 15mg), Frequency:3 times every 12 hours, Duration: 24 hours. Additional Description: Patch Placement: Hairless areas on the arm or forearm
Category
Treatment - Drugs

3

Description
Control group: Name of the drug: Ibuprofen, How to use: Oral tablets (Made by Raha pharmaceutical company), Tablet concentration: 400 mg, Frequency:4 times Every 8 hours, Duration: 24 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Guilan dental school
Full name of responsible person
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Sponsors / Funding sources

1

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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
Rasht 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
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data in this study can be shared.
When the data will become available and for how long
The beginning of the access period is after 1403
To whom data/document is available
The data of this study will be available for use by other researchers.
Under which criteria data/document could be used
In the case of using the results and methods of this

study, the source should be mentioned.

From where data/document is obtainable

Dr. Yasamin Babaee Hemmati, Guilan dental school

What processes are involved for a request to access data/document

Review and satisfaction of the person responsible for the implementation of this study.

Comments