

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating the effect of celecoxib in comparison with acetaminophen on pain management after insertion of first orthodontic wire: a randomized, double-blind, controlled trial

Protocol summary

Study aim

Determining the effectiveness of celecoxib compared to acetaminophen in controlling pain after placing the first orthodontic wire

Design

A parallel-group, double-blind, randomized clinical trial on 70 patients after receiving the first orthodontic wire.

Settings and conduct

To check the level of pain in patients in both groups, a visual analog scale (VAS) was given to the patients to record their pain level at specified times. At the end, the obtained information will be compared with each other, then the results will be analyzed statistically.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Age 12 to 30 years 2- Treatment plan: fixed orthodontics without tooth extraction 3- According to little's irregularity index, it has a moderate rating 4- Starting orthodontic treatment with the lower jaw
Exit criteria: 1- Taking antibiotics and painkillers before orthodontic treatment 2- Pregnant and lactating women 3- Patients with a history of drug allergy 4- Patients with a history of gastrointestinal or kidney ulcer and liver or cardiovascular failure 5- History of drug addiction 6- Not having written informed consent 7. Have periodontal disease

Intervention groups

1. The group that was prescribed celecoxib 200 mg 1 hour before and 6 hours after receiving the orthodontic wire. 2. The group that was prescribed 500 mg of acetaminophen 1 hour before and 6 hours after receiving the orthodontic wire.

Main outcome variables

pain control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221109056454N1**

Registration date: **2023-11-21, 1402/08/30**

Registration timing: **prospective**

Last update: **2023-11-21, 1402/08/30**

Update count: **0**

Registration date

2023-11-21, 1402/08/30

Registrant information

Name

Sara Ghasemzadeh Soroush

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8823 0329

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of celecoxib in comparison with

acetaminophen on pain management after insertion of first orthodontic wire: a randomized, double-blind, controlled trial		pain at the considered times. Because in this study and in general, in the placement of orthodontic wire, the same brand of wire (which is American Orthodontics (AO)) is an important issue, and the performance of the clinician in this case will not be influential or confusing.	
Public title	Evaluating the effect of celecoxib in comparison with acetaminophen on orthodontic pain management	Placebo	Not used
Purpose	Treatment	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: The patient's age is between 12 and 30 years The treatment plan for orthodontic patients should be fixed without tooth extraction. According to little's irregularity index, they should have a moderate rating. Orthodontic treatment should start with the lower jaw. Exclusion criteria: Taking antibiotics and painkillers before orthodontic treatment Pregnant and lactating women Patients with history of allergy to celecoxib or acetaminophen Patients with a history of gastrointestinal or kidney ulcer and liver or cardiovascular failure History of drug addiction Not having written informed consent to participate in the study Patients with periodontal disease	Other design features	
Age	From 12 years old to 30 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	N/A	1	
Groups that have been masked	- Participant - Data analyser	Ethics committee	
Sample size	Target sample size: 70	Name of ethics committee	Research Ethics Committees of School of Dentistry- Tehran University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Tehran- Quds town (west)- between South Flamak and Zarafshan, Simai Iran street- Central headquarters of the Ministry of Health, Treatment and Medical Education, block A, 13th floor
Randomization description	Randomization of patients into two groups under study will be done by permutation block method with size 2x35. The list of random numbers will be prepared by the thesis statistics advisor and will be provided to pharmacist. The website https://www.sealedenvelope.com will be used to generate the list of random numbers. In order to conceal the allocation, the drugs (Celecoxib and Acetaminophen) with the same weight, appearance, color are prepared in identically packaged containers and are coded according to a list of random numbers and assigned to each patient who enters the study sequentially. is allocated and the drug container receives the corresponding code.	City	Tehran
Blinding (investigator's opinion)	Double blinded	Province	Tehran
Blinding description	This study will be double-blind and the statistician will be blind and does not know about the groups under study. Also, the patient will be blind and does not know what medicine he is taking. But in this study, there is no need to blind the dentist because he has no role in evaluating and measuring the outcome of the study and it is the patient who self-reports using the VAS index to measure	Postal code	1467664961
		Approval date	2023-10-21, 1402/07/29
		Ethics committee reference number	IR.TUMS.DENTISTRY.REC.1402.070
		Health conditions studied	
		1	
		Description of health condition studied	Pain after placing the first orthodontic wire
		ICD-10 code	Z46.4
		ICD-10 code description	Encounter for fitting and adjustment of orthodontic device
		Primary outcomes	
		1	
		Description	Overall pain score
		Timepoint	2 hours after wire placement, 6 hours after that, the first night of wire placement, 24 hours after the start, and finally on the second, third, and seventh day.
		Method of measurement	

The patient's score on the severity of orthodontic pain in the general state with the VAS index

2

Description

Pain score in chewing mode

Timepoint

2 hours after wire placement, 6 hours after that, the first night of wire placement, 24 hours after the start, and finally on the second, third, and seventh day.

Method of measurement

Patient's score of orthodontic pain severity in chewing state with VAS index

3

Description

Pain score in biting position

Timepoint

2 hours after wire placement, 6 hours after that, the first night of wire placement, 24 hours after the start, and finally on the second, third, and seventh day.

Method of measurement

Patient score of orthodontic pain severity in biting state with VAS index

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group that was prescribed celecoxib 200 mg 1 hour before and 6 hours after receiving the orthodontic wire.

Category

Treatment - Drugs

2

Description

Intervention group: The group that was prescribed 500 mg of acetaminophen 1 hour before and 6 hours after receiving the orthodontic wire.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences Faculty of Dentistry

Full name of responsible person

Atefeh Saffar Shahroudi

Street address

At the end of North Kargar Street, next to the Atomic

Energy Organization, before the exit of Hakim Sharq Highway, Faculty of Dentistry, Tehran University of Medical Sciences

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Tehran

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dentistry@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

personal

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atefeh Saffar Shahroudi

Position

Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sara Ghasemzadeh Soroush

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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
All non-personally identifiable information
When the data will become available and for how long
6 months after the results are published
To whom data/document is available
Researchers in academic and scientific institutions
Under which criteria data/document could be used
In order to familiarize with the type of study for similar studies and judging
From where data/document is obtainable
Project manager, Dr. Atefeh Saffar Shahroudi a-
shahroudi@tums.ac.ir
What processes are involved for a request to access data/document
Details of the requesting person and the relevant organization, the reason for the request and the process to be carried out
Comments