

# 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

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###### Name of organization / entity

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Iran (Islamic Republic of)

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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. |          |
| <b>Public title</b>                                                                                                      | Evaluating the effect of celecoxib in comparison with acetaminophen on orthodontic pain management                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Placebo</b>                                                                                                                                                                                                                                                                        | Not used |
| <b>Purpose</b>                                                                                                           | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | <b>Assignment</b>                                                                                                                                                                                                                                                                     | Parallel |
| <b>Inclusion/Exclusion criteria</b>                                                                                      | <b>Inclusion criteria:</b><br>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. <b>Exclusion criteria:</b><br>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               | <b>Other design features</b>                                                                                                                                                                                                                                                          |          |
| <b>Age</b>                                                                                                               | From <b>12 years</b> old to <b>30 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Secondary Ids</b>                                                                                                                                                                                                                                                                  |          |
| <b>Gender</b>                                                                                                            | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | empty                                                                                                                                                                                                                                                                                 |          |
| <b>Phase</b>                                                                                                             | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Ethics committees</b>                                                                                                                                                                                                                                                              |          |
| <b>Groups that have been masked</b>                                                                                      | <ul style="list-style-type: none"> <li>Participant</li> <li>Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | <b>1</b>                                                                                                                                                                                                                                                                              |          |
| <b>Sample size</b>                                                                                                       | Target sample size: <b>70</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Ethics committee</b>                                                                                                                                                                                                                                                               |          |
| <b>Randomization (investigator's opinion)</b>                                                                            | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | <b>Name of ethics committee</b>                                                                                                                                                                                                                                                       |          |
| <b>Randomization description</b>                                                                                         | 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 <a href="https://www.sealedenvelope.com">https://www.sealedenvelope.com</a> 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. | Research Ethics Committees of School of Dentistry- Tehran University of Medical Sciences                                                                                                                                                                                              |          |
| <b>Blinding (investigator's opinion)</b>                                                                                 | Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <b>Street address</b>                                                                                                                                                                                                                                                                 |          |
| <b>Blinding description</b>                                                                                              | 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                                                                                                                                                                                                                                                                                                                               | 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                                                                                                 |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>City</b>                                                                                                                                                                                                                                                                           |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Tehran                                                                                                                                                                                                                                                                                |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Province</b>                                                                                                                                                                                                                                                                       |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Tehran                                                                                                                                                                                                                                                                                |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Postal code</b>                                                                                                                                                                                                                                                                    |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 1467664961                                                                                                                                                                                                                                                                            |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Approval date</b>                                                                                                                                                                                                                                                                  |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 2023-10-21, 1402/07/29                                                                                                                                                                                                                                                                |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Ethics committee reference number</b>                                                                                                                                                                                                                                              |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | IR.TUMS.DENTISTRY.REC.1402.070                                                                                                                                                                                                                                                        |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Health conditions studied</b>                                                                                                                                                                                                                                                      |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>1</b>                                                                                                                                                                                                                                                                              |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Description of health condition studied</b>                                                                                                                                                                                                                                        |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Pain after placing the first orthodontic wire                                                                                                                                                                                                                                         |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>ICD-10 code</b>                                                                                                                                                                                                                                                                    |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Z46.4                                                                                                                                                                                                                                                                                 |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>ICD-10 code description</b>                                                                                                                                                                                                                                                        |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Encounter for fitting and adjustment of orthodontic device                                                                                                                                                                                                                            |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Primary outcomes</b>                                                                                                                                                                                                                                                               |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>1</b>                                                                                                                                                                                                                                                                              |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Description</b>                                                                                                                                                                                                                                                                    |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Overall pain score                                                                                                                                                                                                                                                                    |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Timepoint</b>                                                                                                                                                                                                                                                                      |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | 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.                                                                                                                     |          |
|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Method of measurement</b>                                                                                                                                                                                                                                                          |          |

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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##### **Province**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Tabasom Houshmand

##### **Street address**

North Karegar St, Tehran-Iran

##### **City**

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##### **Postal code**

14399-55991

##### **Phone**

+98 21 8801 5801

##### **Email**

sch-dentistry@tums.ac.ir

#### **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**

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**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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## Person responsible for scientific inquiries

**Contact**  
**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Atefeh Saffar Shahroudi  
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Associate professor  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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**Province**  
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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

**Position**  
DDS student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Dentistry  
**Street address**  
Unit 10, No. 2, Second Alley, North Sarsabz St.,  
Marzdaran Blvd  
**City**  
Tehran  
**Province**  
Tehran  
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sarasoroosh20@gmail.com

## 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 Safar 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**