

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### A clinical trial to compare the effectiveness of ibuprofen with curcumin in pain reduction after initial archwire placement in orthodontic patient

#### Protocol summary

##### Study aim

To compare the effectiveness of ibuprofen with curcumin in pain reduction after initial archwire placement in orthodontic patient

##### Design

Totally, 60 patients whose undergoing fixed orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, Mashhad, Iran. In this single-blind, controlled clinical trial, the patients are assigned into parallel groups using simple sampling methods.

##### Settings and conduct

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Female with aged range 14-30 years; no history of systemic disease; nonuse of analgesic.  
Exclusion criteria: Having special medical condition; having drug intolerance; having gastrointestinal disorders.

##### Intervention groups

Intervention group I will receive 400 mg ibuprofen every 8 hours after initial archwire placement. Intervention group II will receive 80 g curcumin tablets every 8 hours after initial archwire placement. The Control group will receive placebo after initial archwire placement.

##### Main outcome variables

Evaluation and comparison of the pain rate in chewing, biting, tipping anterior teeth, and put posterior teeth on each other in 2 and 6 hours, as well as 2 days after the intervention in the three intervention and control groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200609047705N1**  
Registration date: **2020-06-10, 1399/03/21**  
Registration timing: **prospective**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

##### Registration date

2020-06-10, 1399/03/21

##### Registrant information

##### Name

Homan Shafaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3883 2300

##### Email address

shafaeeh@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-21, 1399/04/01

##### Expected recruitment end date

2021-06-22, 1400/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A clinical trial to compare the effectiveness of ibuprofen with curcumin in pain reduction after initial archwire placement in orthodontic patient

**Public title**

The effectiveness of curcumin in pain reduction in orthodontic patient

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Female with aged range 14-30 years No history of systemic disease Nonuse of analgesic

**Exclusion criteria:**

Having a special medical condition Having drug intolerance Having gastrointestinal disorders

**Age**

From **14 years** old to **30 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The subjects will be randomly assigned into three groups of 20 patients with blocks of 2, 4, and 6 using randomization method. A noninvolved researcher will determine the random assignment sequencing in sampling using a statistical analysis system (SAS), computer software. Accordingly, the participants were given codes and assigned to the three intervention and control groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, are chosen as the participants of the study. In this single-blind study, sealed opaque envelopes will be used to conceal the sequencing. The person responsible for data collection is blind to group allocation and the type of intervention.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics Committee of Mashhad University of Medical

Sciences

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9195965919

**Approval date**

2019-10-02, 1398/07/10

**Ethics committee reference number**

IR.MUMS.DENTISTRY.REC.1398.074

**Health conditions studied****1****Description of health condition studied**

Orthodontic

**ICD-10 code**

Z46.5

**ICD-10 code description**

Fitting and adjustment of ileostomy and other intestinal appliances

**Primary outcomes****1****Description**

The pain rate in chewing

**Timepoint**

2, 6 hours, and 2 days after the intervention

**Method of measurement**

Visual Analogue Scale (VAS)

**2****Description**

The pain rate in biting

**Timepoint**

2, 6 hours, and 2 days after the intervention

**Method of measurement**

Visual Analogue Scale (VAS)

**3****Description**

The pain rate in tipping anterior teeth

**Timepoint**

2, 6 hours, and 2 days after the intervention

**Method of measurement**

Visual Analogue Scale (VAS)

**4****Description**

The pain rate in put posterior teeth on each other

**Timepoint**

2, 6 hours, and 2 days after the intervention

#### Method of measurement

Visual Analogue Scale (VAS)

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group: Intervention group I will receive 400 mg ibuprofen every 8 hours after initial archwire placement.

##### Category

Treatment - Drugs

#### 2

##### Description

Intervention group: Intervention group II will receive 80 g curcumin tablets every 8 hours after initial archwire placement.

##### Category

Treatment - Drugs

#### 3

##### Description

Control group: Control group will receive placebo after initial archwire placement.

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Mashhad Faculty of Dentistry Dental Clinic

###### Full name of responsible person

Mohammad Parsa Ghiasi

###### Street address

Dental Clinic of Mashhad Faculty of Dentistry,  
Opposite Mellat Park, Vakilabad Blvd

###### City

Mashhad

###### Province

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###### Postal code

9177948959

###### Phone

+98 51 3883 2300

###### Email

Parsa.ghiasi73@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Mashhad University of Medical Sciences

###### Full name of responsible person

Mohsen Tafaghodi

###### Street address

Vice Chancellor for Research, Mashhad University of  
Medical Sciences, Ghoreishi building, Daneshgah  
Street

###### City

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###### Province

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###### Postal code

9138813944

###### Phone

+98 51 3841 1538

###### Email

vcresearch@mums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

###### Full name of responsible person

Mohammad Parsa Ghiasi

###### Position

Student

###### Latest degree

Medical doctor

###### Other areas of specialty/work

Dentistry

###### Street address

Dental Clinic of Mashhad Faculty of Dentistry,  
Opposite Mellat Park, Vakilabad Blvd

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

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Medical doctor

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mohammad Parsa Ghiasi

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**Email**

Parsa.ghiasi73@yahoo.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**

Not applicable

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Information on the main outcome or the like can be shared

**When the data will become available and for how long**

6 months after printing results

**To whom data/document is available**

Our data will only be available to researchers working at science centers and universities.

**Under which criteria data/document could be used**

Our data will be available for scholars working at science centers and universities.

**From where data/document is obtainable**

Mohammad Parsa Ghiasi provides the data analysis to the applicants via email: Parsa.ghiasi73@yahoo.com

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

Applicants can respond to the email of the respondent and receive a response within a week.

**Comments**