

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

Razavi Khorasan

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

Mashhad

Province

Razavi Khorasan

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3883 2300

Email

Parsa.ghiasi73@yahoo.com

Person responsible for scientific 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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3883 2300

Email

Parsa.ghiasi73@yahoo.com

Person responsible for updating data

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

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3883 2300

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