

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A clinical trial to compare the effectiveness of ibuprofen with low intensity pulsed ultrasound in pain reduction after initial archwire placement in orthodontic patient.

Protocol summary

Study aim

To compare the effectiveness of ibuprofen with low intensity pulsed ultrasound in pain reduction after initial archwire placement in orthodontic patient.

Design

In this double-blinded clinical trial with a control group, 60 patients whose undergoing orthodontic treatment will be selected as parallel groups using a table of random numbers.

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 double-blind study, the participants and responsible for data collection are unaware the kind type of treatment.

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 drug intolerance; having gastrointestinal disorders.

Intervention groups

Intervention group I will receive pulsed ultrasound waves with 100mW/cm² and 1MHz frequency for 5 mints around the mouse after initial archwire placement. This process will be repeated every 24 hours for a week in case of pain. Intervention group II will receive 400 mg ibuprofen every 8 hours after initial archwire placement. 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 in 2 and 6 hours, as well as 2, 3, and 7 days after the intervention in the three intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190825044606N1**

Registration date: **2019-09-06, 1398/06/15**

Registration timing: **prospective**

Last update: **2019-09-06, 1398/06/15**

Update count: **0**

Registration date

2019-09-06, 1398/06/15

Registrant information

Name

Zahra Ahmadi Bemrod

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3883 2300

Email address

ahmadiz921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

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 low intensity pulsed ultrasound in pain reduction after initial archwire placement in orthodontic patient.

Public title

The effectiveness of low intensity pulsed ultrasound 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 drug intolerance Having gastrointestinal disorders

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Sixty patients whose undergoing orthodontic treatment and referring to Dental Clinic of Mashhad Faculty of Dentistry, randomly base on Randomizer.org website assigned three intervention groups. A code was allocated to each of the participants.

Blinding (investigator's opinion)

Double 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 double-blind study, the participants and responsible for data collection are unaware the kind type of treatment.

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

2019-05-01, 1398/02/11

Ethics committee reference number

IR.MUMS.DENTISTRY.REC.1398.045

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, biting, tipping anterior teeth

Timepoint

2 and 6 hours, as well as 2, 3, and 7 days after the intervention

Method of measurement

Based on Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group I will receive pulsed ultrasound waves with 100mW/cm² and 1MHz frequency for 5 mints around the mouse after initial archwire placement. This process will be repeated every 24 hours for a week in case of pain.

Category

Treatment - Devices

2

Description

Intervention group: Intervention group II will receive 400 mg ibuprofen every 8 hours after initial archwire

placement.
Category
Treatment - Drugs

3

Description

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

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Faculty of Dentistry Dental Clinic
Full name of responsible person
Zahra Ahmadi Bemrod
Street address
Dental Clinic of Mashhad Faculty of Dentistry,
Opposite Mellat Park, Vakilabad Blvd
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9177948959
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Email
zhra.ahmadi@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
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1394491388
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
Zahra Ahmadi Bemrod
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry
Street address
Dental Clinic of Mashhad Faculty of Dentistry,
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The total data to be included are the primary and secondary effects to 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 in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Zahra Ahmadi Bemro provides the analysis code to the applicants via email: zhra.ahmadi@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