

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### A clinical trial to compare the effectiveness of ibuprofen with low-level laser on acupuncture points in pain reduction after initial archwire placement in orthodontic patient

#### Protocol summary

##### Study aim

To compare the effectiveness of ibuprofen with low-level laser on acupuncture points in pain reduction after initial archwire placement in orthodontic patient

##### Design

Totally, 80 patients whose undergoing 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 drug intolerance; having gastrointestinal disorders; pregnant and lactating women; having special medical condition.

##### Intervention groups

Intervention group I will receive 810 nm wavelength laser with 200 mW power for 30 seconds around the 6 points area around the root of tooth after initial archwire placement. Intervention group II will receive 810 nm wavelength laser with 200 mW power for 60 seconds in 5 acupuncture points after initial archwire placement. Intervention group III will receive 400 mg ibuprofen every 8 hours after initial archwire placement. Control group will receive laser off in acupuncture points 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, 3, 5 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: **IRCT20200622047886N1**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **prospective**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

##### Registration date

2020-06-29, 1399/04/09

##### Registrant information

##### Name

Melika Hagpanahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3883 2300

##### Email address

ahrarif1@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-07-22, 1399/05/01

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### 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-level laser on acupuncture points in pain reduction after initial archwire placement in orthodontic patient

**Public title**

The effectiveness of low-level laser on acupuncture points 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 Pregnant and lactating women Having special medical condition

**Age**

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

**Gender**

Female

**Phase**

1

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The subjects will be randomly assigned into three groups of 20 patients with blocks of 2, 4, 6 and 8 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 into 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**

Not 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**

2019-11-13, 1398/08/22

**Ethics committee reference number**

IR.MUMS.DENTISTRY.REC.1398.103

## Health conditions studied

1

**Description of health condition studied**

Orthodontic

**ICD-10 code**

Z46.4

**ICD-10 code description**

Fitting and adjustment of orthodontic device

## Primary outcomes

1

**Description**

The pain rate in chewing

**Timepoint**

2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention

**Method of measurement**

Visual Analogue Scale (VAS)

2

**Description**

The pain rate in biting

**Timepoint**

2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention

**Method of measurement**

Visual Analogue Scale (VAS)

### 3

#### **Description**

The pain rate when tipping anterior teeth

#### **Timepoint**

2 and 6 hours, as well as 2, 3, 5 and 7 days after the intervention

#### **Method of measurement**

Visual Analogue Scale (VAS)

### 4

#### **Description**

The pain rate when put posterior teeth on each other

#### **Timepoint**

2 and 6 hours, as well as 2, 3, 5 and 7 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 810 nm wavelength laser with 200 mW power for 30 seconds around the 6 points area around the root of tooth after initial archwire placement.

#### **Category**

Treatment - Other

#### 2

#### **Description**

Intervention group: Intervention group II will receive 810 nm wavelength laser with 200 mW power for 60 seconds in 5 acupuncture points after initial archwire placement.

#### **Category**

Treatment - Other

#### 3

#### **Description**

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

#### **Category**

Treatment - Drugs

#### 4

#### **Description**

Control group: Control group will receive laser off in acupuncture points after initial archwire placement.

#### **Category**

Treatment - Other

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Mashhad Faculty of Dentistry Dental Clinic

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

Melika Hagpanahi

##### **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**

melikah750@gmail.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**

Melika Hagpanahi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Melika Hagpanahi

**Position**

Student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Melika Hagpanahi

**Position**

Student

**Latest degree**

Medical doctor

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**Email**

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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**

Yes - There is 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**

Melika Hagpanahi provides the analysis code to the applicants via email: melikah750@gmail.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**