

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Efficacy of Low-Intensity Pulsed Ultrasound for Orthodontic Pain control

#### Protocol summary

##### Study aim

Efficacy of Low-Intensity Pulsed Ultrasound for Orthodontic Pain Control

##### Design

Randomised trial with control and experiential parallel group, double blinded (patient and outcome assessment)

##### Settings and conduct

22 patients presenting to the Orthodontics Department of Shahid Beheshti School of Dentistry and two private clinics in Tehran. Separators were placed at the mesial and distal of mandibular right and left first molars using separating pliers. low-intensity pulsed ultrasound (LIPUS) was used at one side for 7 minutes and the same device with 0-degree intensity was used as sham for the other side on the facial skin. In this study, the patient and outcome assessment were blinded to the use of on or off the device.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : Absence of periodontal or endodontic problems or active caries, no pain at the onset of study, absence of spacing and presence of tight contacts between the permanent first molar and adjacent teeth, no intake of systemic analgesics, presence of antagonistic tooth, absence of posterior open bite, willingness for participation in the study and patient expressing pain following placement of orthodontic separators. exclusion criteria : detachment of a separator, not filling out the questionnaire and use of analgesics during the study period.

##### Intervention groups

Mandibular right and left First molar in 22 patients

##### Main outcome variables

Orthodontic pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20160626028640N2**

Registration date: **2018-02-10, 1396/11/21**

Registration timing: **retrospective**

Last update: **2018-02-10, 1396/11/21**

Update count: **0**

##### Registration date

2018-02-10, 1396/11/21

##### Registrant information

###### Name

mohammadreza badiie

###### Name of organization / entity

Dentofacial Deformities Research Center,

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2242 7752

###### Email address

mohammadreza.badiie@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-10-23, 1396/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of Low-Intensity Pulsed Ultrasound for Orthodontic Pain control

##### Public title

Efficacy of Low-Intensity Pulsed Ultrasound for Orthodontic Pain control

##### Purpose

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
Absence of periodontal or endodontic problems or active caries, no pain at the onset of study, absence of spacing and presence of tight contacts between the permanent first molar and adjacent teeth no intake of systemic analgesics, presence of antagonistic tooth, absence of posterior open bite, patient expressing pain following placement of orthodontic separators.

**Exclusion criteria:**  
detachment of a separator not filling out the questionnaire use of analgesics during the study period.

**Age**  
From **19 years** old to **32 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**  
Target sample size: **22**  
More than 1 sample in each individual  
Number of samples in each individual: **2**  
Separators were placed at the mesial and distal of mandibular right and left first molars using separating pliers. low-intensity pulsed ultrasound (LIPUS) was used at one side for 7 minutes and the same device with 0-degree intensity was used as sham for the other side on the facial skin.  
Actual sample size reached: **22**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Patients and evaluators are unaware about the consequences of using an ultrasound device on or off.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Shahid Beheshti University of Medical Sciences,  
Daneshjoo BLV, Chamran Highway, Evin

##### City

Tehran

##### Province

Tehran

##### Postal code

19839

##### Approval date

2016-02-10, 1394/11/21

##### Ethics committee reference number

IR.SBMU.RIDS.REC.1394.169

## 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

Orthodontic Pain based on VAS

#### Timepoint

Patients were requested to record their level of pain at one, six and 24 hours and also on days two to seven after placement of separators

#### Method of measurement

visual analog scale (VAS)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Pain evaluation after placement of separator in mesial and distal of mandibular first molar and use of low-intensity pulsed ultrasound (LIPUS) for 7 minutes with degree 100 intensity

#### Category

Treatment - Devices

### 2

#### Description

Control group: Pain evaluation after placement of separator in mesial and distal of mandibular first molar and use of low-intensity pulsed ultrasound (LIPUS) for 7 minutes with 0-degree intensity

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Dental School, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammadreza Badiee

**Street address**

Shahid Beheshti Dental School, Daneshjoo BLV, Chamran Highway, Evin

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+98 21 2242 8638

**Email**

mohammadreza.badiee@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Azita Tehranchi

**Street address**

Dental school, Daneshjoo BLV, Chamran highway, Evin

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azitatehranchi@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammadreza Badiee

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammadreza Badiee

**Position**

Assistant professor

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## Person responsible for updating data

**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Assistant professor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

make this available

**Statistical Analysis Plan**

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

**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**

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

**Data Dictionary**

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

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

No more information

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

No more information

**To whom data/document is available**

No more information

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

No more information

**From where data/document is obtainable**

No more information

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

No more information

**Comments**

No more information