

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The effectiveness of photobiomodulation compared to the elastomeric wafer on the perception of pain during debonding of metal orthodontic brackets

#### Protocol summary

##### Study aim

The effectiveness of photobiomodulation compared to the elastomeric wafer on the perception of pain during debonding of metal orthodontic brackets

##### Design

This study is a one-blinded clinical trial. The study population will include all patients referring to the dental department of Kermanshah Dental School. 112 eligible patients will be selected conveniently and randomly assigned to four groups (three intervention groups and one control group).

##### Settings and conduct

This study, which will be conducted at the Kermanshah School of Dentistry, is one-blinded one, that patients will be kept blind to the allocation of study groups and treatment methods. At the beginning of the study, the amount of pain is recorded in a checklist

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Having all permanent teeth; People who are undergoing fixed upper and lower jaw orthodontic treatment with a type of bracket; People who have finishing Archwire for at least two months  
Exclusion criteria: Taking the drug periodically or taking the medication for 24 hours before the study; Have a cleft lip or cleft palate; Smokers or alcoholics; People who have taken antibiotics for the past 6 months or who have had periodontal treatment in the past year

##### Intervention groups

In the first intervention group, the elastomeric wafer of silicon wafers is used that placed between the arches and the patient is told to bite it firmly during debonding. In the second intervention group, they are treated with a low-power laser for at least 30 seconds to one minute before debonding, in which the laser is irradiated with 16 joules/cm<sup>2</sup> of energy in the buccal and palate region. In the third intervention group, the laser used is off. The control group will not receive any intervention.

#### Main outcome variables

Perception of pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N149**

Registration date: **2020-04-26, 1399/02/07**

Registration timing: **prospective**

Last update: **2020-04-26, 1399/02/07**

Update count: **0**

##### Registration date

2020-04-26, 1399/02/07

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

froughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-28, 1399/02/09

##### Expected recruitment end date

2020-07-30, 1399/05/09

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of photobiomodulation compared to the elastomeric wafer on the perception of pain during debonding of metal orthodontic brackets

**Public title**

The effectiveness of photobiomodulation compared to the elastomeric wafer on the perception of pain during debonding of metal orthodontic brackets

**Purpose**

Treatment

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

Having all permanent teeth People who are undergoing fixed upper and lower jaw orthodontic treatment with a type of bracket People who have finishing Archwire for at least two months

**Exclusion criteria:**

Taking the drug periodically or taking the medication for 24 hours before the study have a cleft lip or cleft palate Smokers or alcoholics People who have taken antibiotics for the past 6 months or who have had periodontal treatment in the past year People with an index plate above 4

**Age**

From **13 years** old to **21 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **112**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Balanced block randomization

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Patients have been kept blind about the allocation of study groups and treatment methods.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2020-02-03, 1398/11/14

**Ethics committee reference number**

ir.kums.rec.1399.051

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

metal orthodontic

**ICD-10 code**

Z46.4

**ICD-10 code description**

Encounter for fitting and adjustment of orthodontic device

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

Perception of pain

**Timepoint**

At baseline, Immediately after debonding on each tooth and 1 week after removing the brackets

**Method of measurement**

Using visual scale of pain (VAS)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the first intervention group, the elastomeric wafer of silicon wafers is used that placed between the arches and the patient is told to bite it firmly during debonding.

**Category**

Treatment - Other

## 2

### Description

In the second intervention group, they are treated with a low-power laser for at least 30 seconds to one minute before debonding, in which the laser is irradiated with 16 joules/ cm<sup>2</sup> of energy in the buccal and palate region

### Category

Treatment - Other

## 3

### Description

In the third intervention group, the laser used is off.

### Category

Treatment - Other

## 4

### Description

The control group will not receive any intervention.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

School of Dentistry

##### Full name of responsible person

Ermia Rezae Shirazi

##### Street address

Shariati St., School of Dentistry

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713954658

##### Phone

+98 83 3722 7151

##### Email

ermia.rezae@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Farid Najafi

##### Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3836 0014

##### Email

fnajafi@kums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

##### Full name of responsible person

Ermia Rezaea Shirazi

##### Position

School of Dentistry

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

Shariati St., School of Dentistry

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713954658

##### Phone

+98 83 3722 7151

##### Email

ermia.rezae@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Amin Golshah

##### Position

Faculty member of Kermanshah University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthodontic

**Street address**

Shariati St., School of Dentistry

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713954658

**Phone**

0098833729659

**Email**

amin.golshah@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Ermia Rezae Shirazi

**Position**

medical student

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Shariati St., School of Dentistry

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6713954658

**Phone**

+98 83 3722 7151

**Email**

ermia.rezae@gmail.com

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

Yes - There is 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**

Not applicable

**Data Dictionary**

Not applicable

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

The main outcomes of the study will be shared.

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

6months

**To whom data/document is available**

If requested, results will be made available to other academic researchers

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

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

**Comments**