

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of photobiomodulation on the perception of pain during orthodontic interproximal tooth reduction; a double-blinded randomized controlled trial

#### Protocol summary

##### Study aim

The effect of photobiomodulation on the perception of pain during orthodontic interproximal tooth reduction

##### Design

This is a randomized, double-blind clinical trial with a parallel design and a control group. Phase 2-3, this randomized study, will be conducted on 24 eligible patients. For randomization, simple random is used, and the participants are assigned to three groups (one intervention group and two control groups).

##### Settings and conduct

This study, which will be conducted in the clinic of the Faculty of Dentistry in Kermanshah, is a double-blinded. The patients and the operator are blinded to whether the laser light is on or off. Interproximal stripping will be done manually by an orthodontist using manual abrasive strips for all patients.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed consent; Bolton dispute; Slight crowding in the lower incisor area; Mild misalignment between arches and a need for interproximal stripping; Centerline difference  
Exclusion criteria: Patients with removable orthodontic appliances; History of taking anticonvulsant and antidepressant drugs; Active herpes simplex infection in the mouth (simplex and zoster); History of temporomandibular arthritis

##### Intervention groups

The intervention group includes orthodontic candidate patients who will receive low-power laser therapy at least 3 minutes before interproximal stripping, a diode laser (Epi X, Biolase, USA) with a wave length of 940 nm is used, and laser radiation with an energy of 32 J/cm<sup>2</sup> (180 seconds) ) will be done to the labial and lingual areas. The first control group includes orthodontic candidate patients who will be subjected to off-laser. The second control group includes orthodontic candidate patients

who will undergo interproximal stripping without using a laser.

##### Main outcome variables

The Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N192**

Registration date: **2023-01-18, 1401/10/28**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-01-18, 1401/10/28**

Update count: **0**

##### Registration date

2023-01-18, 1401/10/28

##### 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

2023-01-10, 1401/10/20

##### Expected recruitment end date

2023-05-10, 1402/02/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of photobiomodulation on the perception of pain during orthodontic interproximal tooth reduction; a double-blinded randomized controlled trial

**Public title**

The effect of photobiomodulation on the perception of pain during orthodontic

**Purpose**

Treatment

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

Informed consent Bolton dispute Slight crowding in the lower incisor area Mild misalignment between arches and a need for interproximal stripping Centerline difference

**Exclusion criteria:**

Patients with removable orthodontic appliances History of taking anticonvulsant and antidepressant drugs Active herpes simplex infection in the mouth (simplex and zoster) History of temporomandibular arthritis

**Age**

From **18 years** old to **30 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Using the simple random method. The names of the participants are written on the card. The cards are put into a box that cannot be seen from outside. One of the colleagues of the plan is asked to remove one card from the container at a time. The names of the 8 cards that are selected first are placed in the first intervention group, the second 8 selected cards are placed in the first control group, and the remaining 8 in the second control group.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****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**

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

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Approval date**

2022-10-11, 1401/07/19

**Ethics committee reference number**

IR.KUMS.REC.1401.344

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

Orthodontic Pain

**ICD-10 code**

Z51.8

**ICD-10 code description**

Encounter for other specified aftercare

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

The pain

**Timepoint**

The first, second, fourth and seventh days after laser radiation

**Method of measurement**

Using a visual pain scale

**Secondary outcomes**

empty

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

The intervention group will receive low-power laser therapy at least 3 minutes before interproximal stripping, a diode laser (Epi X, Biolase, USA) with a wavelength of 940 nm is used, and laser radiation with an energy of 32 J/cm<sup>2</sup> (180 seconds) ) will be done to the labial and lingual areas.

**Category**

Treatment - Other

## 2

### Description

The first control group will be subjected to off-laser.

### Category

Treatment - Other

## 3

### Description

The second control group will undergo interproximal stripping without any use of a laser.

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dental faculty clinic

##### Full name of responsible person

Dr. Amin Golshah

##### Street address

Faculty of Dentistry, Shariati Ave

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6713954658

##### Phone

+98 83 3729 6591

##### Email

amin.golshah@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Cyrus Jalili

##### Street address

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

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847141

##### Phone

+98 83 3836 0014

##### Email

cjalili@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

Amin Golshah

##### Position

Member of the teaching faculty of Kermanshah  
University of Medical Sciences

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

Faculty of Dentistry, Shariati Ave

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##### Province

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amin.golshah@gmail.com

## Person responsible for scientific inquiries

#### Contact

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Kermanshah University of Medical Sciences

##### Full name of responsible person

Dr. Amin Golshah

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Amin Golshah

**Position**

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University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Faculty of Dentistry, Shariati Ave

**Sharing plan**

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available