

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/cm² (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/cm² (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

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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

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6715847141

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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

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Faculty of Dentistry, Shariati Ave

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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