

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/cm² 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

fforoughi@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/ cm² 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

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Shariati St., School of Dentistry

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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

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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

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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

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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

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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