

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Effect of different photobiomodulation laser therapy in orthodontic pain reduction caused by elastic separator: randomized control trial

Protocol summary

Study aim

Effect of different photobiomodulation laser therapy in orthodontic pain reduction caused by elastic separator: randomized control trial

Design

This study is a randomized clinical trial with a parallel design and a control group. This randomized study will be performed on 24 patients. For randomization, online software for generating random numbers is used and participants are assigned to three intervention groups and one control group.

Settings and conduct

This study, which will be performed in the specialized dental clinic of Kermanshah University of Medical Sciences, is double-blind. In this double-blind study, researchers and patients are kept blind as to what type of treatment they will receive. Also, researchers and participants have no role in the process of randomization and assignment of intervention groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: In both jaws, all teeth are fully erupted by the second molar before treatment, and the second premolars, first and second molars are in contact, allowing 2 elastic separator in the mesial and distal of the first four molars. Exclusion criteria: Dependence on psychotropic drugs; History of anticonvulsant and antidepressant use; Chronic systemic diseases such as liver, lung, heart and kidney diseases etc...; History of neuropathic disorders, glossopharyngeal neuralgia, etc...; Diabetes and metabolic diseases

Intervention groups

In the first intervention group, a laser quadrant unit is turned on; Apply the laser for the first quarter of 120 seconds (60 seconds for each buccal or lumbar). In the second intervention group, 60 seconds lingual or palatal, and we reduce the time by half (that is, 30 seconds for each buccal or lumbar). In the third intervention group, a silent laser is used. Laser is not performed in the control group.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N180**

Registration date: **2022-02-08, 1400/11/19**

Registration timing: **prospective**

Last update: **2022-02-08, 1400/11/19**

Update count: **0**

Registration date

2022-02-08, 1400/11/19

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-05-31, 1401/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Effect of different photobiomodulation laser therapy in orthodontic pain reduction caused by elastic separator: randomized control trial

Public title
Effect of different photobiomodulation laser therapy in orthodontic pain reduction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 30 years In both jaws, all teeth are fully erupted by the second molar before treatment, and the second premolars, first and second molars are in contact, allowing to put 2 elastic separators in the mesial and distal of the first four molars.
Exclusion criteria:
Dependence on psychotropic drugs History of taking anticonvulsants and antidepressants History of chronic systemic diseases such as liver, lung, heart and kidney diseases, etc. History of neuropathic disorders, glossopharyngeal neuralgia, etc.). Diabetes and metabolic diseases Infectious diseases, autoimmune diseases, immune defects, AIDS Pregnancy Symptoms of infection or periodontal disease History of tooth extraction from 2 weeks ago

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
Generate random numbers using online software. Divided quadrants will be drawn on 24 sheets of paper (in the number of patients) and random numbers will be written on each quadrant. Then, each of the papers will be placed in an envelope. Each patient removes an envelope and based on that, the method of placement of elastic separator will be done in each quadrant. The production of random numbers and allocation concealment will be done by an impartial observer.

Blinding (investigator's opinion)
Double blinded

Blinding description
Laser light with a wavelength of 940 nm is not visible to the human eye and no heat is generated. Therefore, both the patient and the operator were blind (on or off) when using the laser. The laser radiation will be performed by

the dentist's assistant. The operator will not know which quadrant is treated with the laser on and which is treated with the laser off. However, complete blinding of the patient will not be possible, and only blinding for laser on or off will be possible.

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
2022-01-10, 1400/10/20

Ethics committee reference number
IR.KUMS.REC.1400.755

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
Pain

Timepoint
0, 1, 6, 12, 24, 48 hours after Separator placement

Method of measurement
Using Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

In the first intervention group, a laser quadrant unit is turned on; Apply the laser for the first quarter of 120 seconds (60 seconds for each buccal or lumbar). At each buccal or lingual surface, two points, one point 5 mm from the gingival margin and one point near the apex, the laser will be applied.

Category

Treatment - Other

2

Description

In the second intervention group, 60 seconds lingual or palatal, and we reduce the time by half (that is, 30 seconds for each groceries). At each buccal or lingual surface, two points, one point 5 mm from the gingival margin and one point near the apex, the laser will be applied.

Category

Treatment - Other

3

Description

In the third intervention group, a silent laser is used. At each buccal or lingual surface, two points, one point 5 mm from the gingival margin and one point near the apex, the laser will be applied.

Category

Treatment - Other

4

Description

Laser is not performed in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Specialized clinic of the School of Dentistry

Full name of responsible person

Dr. Amin Golshah

Street address

Faculty of Dentistry, Shariati Ave

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6713954658

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amin.golshah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

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

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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

Dr. Amin Golshah

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

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

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Faculty member of Kermanshah University of Medical Sciences

Latest degree

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Other areas of specialty/work

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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 more 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