Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Investigating the Effectiveness of Photobiomodulation Therapy on Pain Reduction After Miniscrew Placement in Orthodontic Patients: A Randomized Clinical Trial

Protocol summary

Study aim
To evaluate the effectiveness of photobiomodulation therapy in reducing pain following miniscrew placement in orthodontic patients using a split-mouth design.

Design
Randomized, double-blind, placebo-controlled, split-mouth clinical trial with 18 patients; randomization using block sizes of 2, 4, and 6 via sealedenvelope.com; not applicable for clinical trial phase.

Settings and conduct
The study is conducted in private orthodontic clinic on 18 patients requiring miniscrew placement. Photobiomodulation or placebo is applied post-miniscrew insertion by a trained operator. Participants and outcome assessors are blinded using identical laser application protocols. Data collection includes pain assessment via Visual Analog Scale and gingival index evaluation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients requiring miniscrew placement during orthodontic treatment, no prior orthodontic treatment before the study, no radiographic evidence of bone loss, no active dental caries, no periodontal diseases, adequate oral hygiene; Exclusion criteria,: hypersensitivity to laser light, pregnancy.

Intervention groups
Intervention group: Photobiomodulation therapy using a diode laser with 940 nanometers wavelength, 300 milliwatts power, and 31.7 joules per square centimeter energy density applied for 180 seconds to the tissue surrounding the miniscrew on one side of the mouth. Control group: Placebo with inactive laser applied for 180 seconds to the tissue surrounding the miniscrew on the opposite side of the mouth with identical appearance and procedure.

Main outcome variables
Pain intensity measured by Visual Analog Scale immediately after miniscrew placement; at 1 hour; 12 hours; 24 hours.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250605066076N1**
Registration date: **2025-06-10, 1404/03/20**
Registration timing: **prospective**

Last update: **2025-06-10, 1404/03/20**
Update count: **0**
Registration date
2025-06-10, 1404/03/20

Registrant information
Name
Perham Shirvani
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-06-22, 1404/04/01
Expected recruitment end date
2025-12-22, 1404/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effectiveness of Photobiomodulation Therapy on Pain Reduction After Miniscrew Placement in Orthodontic Patients: A Randomized Clinical Trial

Public title
Effect of Photobiomodulation on Pain Reduction After Miniscrew Placement in Orthodontics

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients requiring miniscrew placement during orthodontic treatment No prior orthodontic treatment before the study No radiographic evidence of bone loss No active dental caries No periodontal diseases Adequate oral hygiene

Exclusion criteria:
Hypersensitivity to laser light Pregnancy

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **18**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each participant provides two samples, corresponding to the two sides of the mouth (left and right). One side receives active photobiomodulation (laser on), and the other receives placebo (laser off), allowing for a direct comparison of pain and gingival index outcomes within the same individual.

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed using two series of random numbers in blocks of 2, 4, and 6, generated via www.sealedenvelope.com. The first series determines the side of the mouth for intervention, and the second series determines the type of intervention (active laser or placebo). Allocation concealment is ensured using sealed opaque envelopes, each containing codes A or B. Randomization is conducted by an independent researcher not involved in treatment or assessment. Patient enrollment is performed by an orthodontist, and intervention allocation is conducted by a trained assistant.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is designed as a double-blind trial. Participants are unaware of the intervention allocation (active laser or placebo) on each side of the mouth, as the laser device used for both active and placebo interventions has identical appearance, sound, and application procedure. Outcome assessors, responsible for evaluating pain using the Visual Analog Scale (VAS) and assessing the gingival index, are blinded to the intervention allocation, as data collection forms and clinical examinations do not indicate which side received the active or placebo treatment. Blinding is maintained through standardized laser application protocols and sealed randomization codes managed by an independent researcher. The clinical caregiver (orthodontist administering the intervention) and the data analyst are not blinded due to the requirements of intervention delivery and data analysis.

Placebo
Used

Assignment
Parallel

Other design features
This study employs a split-mouth design, where each participant simultaneously receives both the intervention (active photobiomodulation) and placebo (inactive laser) on different sides of the mouth. This design minimizes inter-individual variability and enhances the precision of the results by allowing each participant to serve as their own control.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences

Street address
Ethics Committee, Medical Faculty, Daneshgah Street, Shahid Shiroodi Boulevard

City
Kermanshah

Province
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Postal code
6714869914

Approval date
2025-05-13, 1404/02/23

Ethics committee reference number
IR.KUMS.REC.1404.137

Health conditions studied

1

Description of health condition studied
Pain following miniscrew placement in orthodontic treatment

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain intensity following miniscrew placement in orthodontic treatment
Timepoint
Immediately after miniscrew placement, 1 hour after miniscrew placement, 12 hours after miniscrew placement, 24 hours after miniscrew placement
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Gingival inflammation around the miniscrew placement site as measured by the modified gingival index, scored as: 0 (no inflammation, pink gingiva, no visible biofilm), 1 (mild inflammation, red gingiva without bleeding), 2 (moderate inflammation, severe red gingiva with mild bleeding on probing), 3 (severe inflammation or miniscrew failure, pronounced bleeding, swelling).
Timepoint
7 days after miniscrew placement
Method of measurement
Modified Gingival Index

2

Description
Presence of redness around the miniscrew placement site
Timepoint
7 days after miniscrew placement
Method of measurement
Clinical examination by an orthodontist

3

Description
Presence of blisters around the miniscrew placement site
Timepoint
7 days after miniscrew placement
Method of measurement
Clinical examination by an orthodontist

Intervention groups

1

Description
Intervention group: Photobiomodulation therapy using a diode laser with a wavelength of 940 nanometers, power of 300 milliwatts, and energy density of 31.7 joules per square centimeter in continuous wave mode, applied for 180 seconds to the tissue surrounding the miniscrew on one side of the mouth. The laser is administered with a spot size of 1.7 square centimeters, moving from the surrounding tissue toward the center, by a trained operator.
Category
Treatment - Devices

2

Description
Control group: Placebo with an inactive laser applied for 180 seconds to the tissue surrounding the miniscrew on the opposite side of the mouth. The procedure mimics the active laser application in appearance, sound, and duration to maintain blinding, performed by a trained operator.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Golshah Dental Clinic
Full name of responsible person
Amin Golshah
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Unit 3, Second Floor, Arshia Building, Zarafshani Alley, Dabir Azam Street, Dabir Azam
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Position
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Individual Participant Data, Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analysis Codes, and Data Dictionary: The individual participant data (IPD) will include de-identified data on pain intensity (Visual Analog Scale scores), gingival index, inflammation, redness, and blisters, as

well as demographic variables (age, gender) and pain catastrophizing scale scores. The study protocol will detail the methodology, including the split-mouth design, photobiomodulation parameters, and outcome assessments. The statistical analysis plan will describe the statistical tests (e.g., paired t-test, Wilcoxon, GEE) and software (SPSS) used. The informed consent form will be shared in its final approved version. The clinical study report will summarize findings post-study completion. Analysis codes will include SPSS syntax for all statistical analyses. The data dictionary will define all variables, their coding, and measurement units.

When the data will become available and for how long

Data and documents will be available starting six months after the publication of the primary study results and will remain accessible for five years thereafter.

To whom data/document is available

Researchers affiliated with academic or scientific institutions, including universities and research centers, who are conducting non-commercial research related to orthodontics, pain management, or photobiomodulation.

Under which criteria data/document could be used

Data and documents may be used for secondary analyses, meta-analyses, or methodological reviews related to orthodontic pain management or photobiomodulation. Access requires a formal request outlining the research objectives, analysis plan, and ethical approval for the proposed study. Recipients must sign a data use agreement ensuring confidentiality, non-commercial use, and no attempt to re-identify participants. Data sharing will comply with ethical standards and Iranian regulations.

From where data/document is obtainable

Requests should be submitted via email to Dr. Fatemeh Azizi at azizi3889@gmail.com. Alternatively, contact the Research Office at Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard, Kermanshah, Iran, phone: +98 83 34276301.

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

Applicants must submit a written request detailing the research purpose, analysis plan, and ethical approval. The request will be reviewed by the study's principal investigator (Dr. Fatemeh Azizi) and the Kermanshah University of Medical Sciences Ethics Committee within four weeks. If approved, a data use agreement will be signed, and data/documents will be shared via a secure electronic platform within two weeks of agreement. Applicants will be notified of the decision and expected timeline.

Comments

All shared data will be anonymized to protect participant privacy. The study team reserves the right to reject requests that do not align with the study's ethical or scientific objectives. Shared data must not be redistributed without prior approval.