Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effectiveness of Photobiomodulation therapy (PBMT) in pain management following orthodontic tooth extraction with immediate traction

Protocol summary

Study aim

To compare mean pain scores between the Photobiomodulation therapy (PBMT)-treated side and the untreated control side, measured at baseline, immediately post-activation (T0), 24 hours (T1), and 48 hours (T2) post-canine retraction, in patients undergoing bilateral upper first premolar extraction with immediate canine traction.

Design

A single-blind, non-randomized, controlled clinical trial with a split-mouth design of 32 patients, with alternating-side allocation of intervention and control

Settings and conduct

Setting: Single-center study in the Department of Orthodontics, Armed force institute of dentistry, Pakistan. Conduct: After written consent, 32 patients undergo bilateral extraction with immediate traction, receiving active Photobiomodulation therapy (PBMT) on one side (alternated between consecutive patients) and untreated group using placebo, with pain recorded by the patient on a VAS at [time points].

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with good periodontal health.Patients scheduled for fixed orthodontic treatment involving canine retraction. Exclusion criteria:Patients with any systemic medical condition that may affect pain perception or healing. • Patients taking analgesics, anti-inflammatory drugs, antidepressants, or anxiolytics within 48 hours prior to the procedure

Intervention groups

Group 1 (Experimental): Active Photobiomodulation therapy (PBMT)- applied to the extraction site on one side after extraction with immediate traction, with the side alternated between consecutive patients (n = 32).Group 2 (placebo): Same probe position, duration, and eyewear on the contralateral side, with the device switched off (n = 32).

Main outcome variables

Pain intensity on a Visual Analogue Scale (0-100 mm, continuous), self-recorded by the patient on each side at baseline, immediately post-activation (T0), 24 h (T1) and 48 h (T2).

General information

Reason for update

Acronym

PAIN-PBM

IRCT registration information

IRCT registration number: **IRCT20250415065344N1**
Registration date: **2026-11-07, 1405/08/16**
Registration timing: **retrospective**

Last update: **2026-11-07, 1405/08/16**
Update count: **0**

Registration date

2026-11-07, 1405/08/16

Registrant information

Name

Ayesha hafeez

Name of organization / entity

Armed force institute of dentistry

Country

Pakistan

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+92 302 2027760

Email address

ayeshahafeez5678@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-10-19, 1405/07/27

Expected recruitment end date

2026-10-30, 1405/08/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Photobiomodulation therapy (PBMT) in pain management following orthodontic tooth extraction with immediate traction

Public title

Photobiomodulation Therapy (PBMT) for Postoperative Pain Control After Extraction with Immediate Orthodontic Traction: A Split-Mouth Non-Randomized Controlled Trial

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

• Patients with good periodontal health (no active gingivitis or periodontitis). • Patients scheduled for fixed orthodontic treatment involving canine retraction.

Exclusion criteria:

• Patients with any systemic medical condition that may affect pain perception or healing (e.g., diabetes, autoimmune conditions). • Patients taking analgesics, anti-inflammatory drugs, antidepressants, or anxiolytics within 48 hours prior to the procedure. • Patients with a history of psychological or neurological conditions that may alter pain response • Patients with dental anomalies in the canine or premolar region (impaction, ectopic eruption, root malformations). • Patients with poor oral hygiene, active infection, or periodontal disease. • Patients who have undergone previous laser therapy or adjunctive acceleration techniques (MOPs, piezocision, vibration devices).

Age

From **14 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **32**

More than 1 sample in each individual

Number of samples in each individual: **2**

A total of 32 orthodontic patients requiring bilateral extractions with immediate traction will be enrolled. Each participant serves as their own control, contributing two extraction sites: one receives active PBMT and the contralateral site receives sham laser. This yields 32 PBMT sites and 32 sham sites (64 sites in total). Side allocation is alternated between consecutive participants.”

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single-blind study in which only the patient is masked. On each side, the laser probe is positioned over the extraction site for the same duration, with the same protocol, and with the operator in the same position. On the active side the device emits laser energy, while on the placebo side the device is switched off (or set to zero output), and the audible indicator is identical on both sides. Both the patient and the room lighting are managed so the patient cannot see the device display, and the patient wears protective eyewear on both sides, which keeps the sides indistinguishable to them.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethical committee of armed force institute of dentistry pakistan

Street address

Armed force institute of dentistry Rawalpindi pakistan

City

Rawalpindi

Postal code

46100

Approval date

2025-05-20, 1404/02/30

Ethics committee reference number

918/Trg dated 13 may 2020

Health conditions studied

1

Description of health condition studied

Pain following premolar extraction in orthodontic patients with malocclusion undergoing canine retraction

ICD-10 code

M26.4

ICD-10 code description

Malocclusion, unspecified

Primary outcomes

1

Description

Pain intensity on photobiomodulation therapy (PBMT)-treated side compared with the control side after extraction with immediate canine traction, expressed as the mean difference in pain scores between sides

Timepoint
Baseline (before canine retraction), immediately post-activation (T0), 24 hours (T1) and 48 hours (T2) after canine retraction.

Method of measurement
atient self-reported Visual Analogue Scale (0-100 mm, higher scores mean more pain), recorded separately for each side on the standardized data collection form.

Secondary outcomes

1

Description
Pattern of pain across time points within the Photobiomodulation therapy (PBMT) side and the control side, including the time of peak pain (side × time interaction).

Timepoint
Baseline, T0, 24 hours (T1) and 48 hours (T2) after canine retraction.

Method of measurement
patient-reported VAS (0-100 mm) on ANNEX-B, analyzed by two-way repeated measures ANOVA (Side × Time) or the Friedman test.

Intervention groups

1

Description
Photobiomodulation therapy (PBMT) using a diode laser in near-infrared, continuous-wave, non-contact mode with a wavelength of 810 nm, applied to the extraction socket on the experimental side of each patient 5 days after extraction of the ipsilateral tooth (on the day canine retraction begins on that side). The laser was applied at three points (mesial, distal and occlusal of the socket) in a single session, on the day canine retraction began (5 days after extraction). Device: [laser model, manufacturer]; output power: 200 mW; spot size: 0.5 cm^2; power density: 400 mW/cm^2; time per point: 20 seconds; total irradiation time: 60 seconds per socket; energy per point: 4 J; energy density: 8 J/cm^2 per point; total energy: 12 J per socket; tip-to-tissue distance: 1 cm. All applications were delivered by the same trained operator using a standardized protocol.

Category
Treatment - Devices

2

Description
Control group:Placebo laser procedure on the contralateral extraction socket of the same patient, performed in a separate session from the active side, 5 days after extraction of the contralateral tooth (on the day canine retraction begins on that side). The same diode laser device, trained operator and standardized protocol were used, with the tip held at the same three points (mesial, distal and occlusal of the socket) for 20 seconds per point (total 60 seconds per socket) at the same tip-to-tissue distance of 1 cm, but with the laser switched off so that no energy was emitted (0 mW, 0 J). The patient was blinded to which side received active PBMT.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Orthodontics, Armed Forces Institute of Dentistry (AFID), Rawalpindi, Pakistan.

Full name of responsible person
Dr Ayesha Hafeez

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Rawalpindi, pakistan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Department of Orthodontics, Armed Forces Institute of Dentistry (AFID), Rawalpindi, Pakistan.

Full name of responsible person
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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
Department of Orthodontics, Armed Forces Institute of Dentistry (AFID), Rawalpindi, Pakistan.

Proportion provided by this source
100

Public or private sector
Private

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
Department of Orthodontics, Armed Forces Institute of Dentistry (AFID), Rawalpindi, Pakistan.
Full name of responsible person
Dr Ayesha Hafeez
Position
Registrar orthodontics
Latest degree
Medical doctor
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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
De-identified individual participant data (IPD) from the PBMT split-mouth trial: VAS pain scores (0-100 mm) for the PBMT side and the control side at baseline, T0, 24 h and 48 h, together with age and sex. Names, addresses and other identifiers are excluded. The study protocol and statistical analysis plan will also be shared.
When the data will become available and for how long
When the data will become available and for how long - English Starting 6 months after publication of the main results and remaining available for 5 years.
To whom data/document is available
Researchers and clinicians working in academic or research institutions, including students and healthcare organisations, for non-commercial purposes.
Under which criteria data/document could be used
Data may be used for academic, non-commercial

research, such as meta-analyses or secondary analyses of pain outcomes. Requesters must send a written request to the principal investigator stating the research purpose and agree not to attempt to identify participants. Requests will be reviewed by the principal investigator and the study supervisor, with approval from the institutional ethical committee.

From where data/document is obtainable

By email request to the principal investigator, Dr Ayesha Hafeez, Department of Orthodontics, Armed Forces Institute of Dentistry, Rawalpindi, Pakistan, at [ayeshahafeez5678@gmail.com]. Data will be provided as an SPSS or Excel file

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

The requester sends a written request by email to the principal investigator, Dr Ayesha Hafeez, stating their name, institution, research question and intended analysis. The principal investigator and the study supervisor review the request for scientific validity and non-commercial use, and confirm the approval of the institutional ethical committee. A decision is communicated within 4 weeks. If approved, the requester signs a data use agreement committing to non-commercial use, no attempt to re-identify participants, and no onward sharing. The de-identified dataset (SPSS or Excel file) and the protocol and statistical analysis plan are sent to the requester by secure email or a secure file-sharing link.

Comments