Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of 970-nm diode laser photobiomodulation combined with a neutral gel on pain perception during buccal infiltration anesthesia in maxillary anterior teeth

Protocol summary

Study aim

Evaluation of the effect of photobiomodulation using a 970-nm diode laser, combined with a neutral gel, on the perception of pain caused by buccal infiltration anesthesia in the maxillary anterior teeth.

Design

Phase II, randomized, single-blind, sham-controlled clinical trial with a 2×2 factorial, four parallel-arm, conducted on 128 patients. Allocation was performed using block randomization with variable block sizes (4 and 8) generated via Sealed Envelope.

Settings and conduct

This single-blind randomized trial will be conducted in a dental clinic. Patients are randomly assigned to four groups and receive standardized buccal infiltration anesthesia by one operator. Blinding is achieved using sham laser and neutral gel, making patients unaware of group allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Adults ≥18 years requiring maxillary anterior buccal infiltration anesthesia, ASA I–II, able to complete VAS and DAI. Exclusion criteria: Refusal of consent, allergy/contraindication to local anesthetics or epinephrine, uncontrolled systemic disease, or infection/inflammation/lesions at the injection site.

Intervention groups

Group 1: Active 970-nm diode laser without gel, followed by buccal infiltration anesthesia. Group 2: Neutral gel + sham laser, then anesthesia. Group 3: Neutral gel + active laser, then anesthesia. Group 4: Sham laser without gel (control), then anesthesia.

Main outcome variables

1. Pain intensity during needle insertion measured using a 0–10 Visual Analog Scale (VAS). 2. Pain intensity during anesthetic solution injection measured using a 0–10 Visual Analog Scale (VAS).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260614069786N1**
Registration date: **2026-07-06, 1405/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2026-07-06, 1405/04/15**
Update count: **0**

Registration date

2026-07-06, 1405/04/15

Registrant information

Name

Nazanin Mohamadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-06, 1405/04/15

Expected recruitment end date

2027-01-05, 1405/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the effect of 970-nm diode laser photobiomodulation combined with a neutral gel on pain perception during buccal infiltration anesthesia in maxillary anterior teeth

Public title
Does photobiomodulation with a 970-nm diode laser and neutral gel reduce pain during local anesthetic injection in maxillary anterior teeth?

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adults aged 18 years and older. Patients requiring buccal infiltration anesthesia in the maxillary anterior region for dental treatment. American Society of Anesthesiologists (ASA) physical status I or II. Ability to understand and complete the Visual Analog Scale (VAS) and Dental Anxiety Inventory (DAI). Provision of written informed consent.

Exclusion criteria:
Lack of informed consent to participate in the study. Known allergy to local anesthetic agents or contraindication to the use of epinephrine. Uncontrolled systemic disease requiring specialized medical management. Presence of inflammation, infection, abscess, wound, or any soft tissue lesion at the injection site. Use of analgesics/NSAIDs, corticosteroids, sedatives, or anti-anxiety medications within 24 hours prior to the intervention. Alcohol or stimulant substance use within the previous 24 hours. Patients with acute dental pain, swelling, or requiring emergency dental treatment.

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be randomly allocated to one of the four study groups using variable block randomization with block sizes of 4 and 8. The random allocation sequence will be generated by an independent statistician. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes (SNOSE).

Blinding (investigator's opinion)
Single blinded

Blinding description
Participants will be blinded to active versus sham laser allocation. Due to the nature of the intervention, operator blinding is not feasible.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Dentistry-Tehran university of Medical Science

Street address
Faculty of Dentistry, Tehran University of Medical Sciences End of North Kargar Street, beside the Atomic Energy Organization of Iran, Before the East Hakim Expressway Exit, Tehran, Iran

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Approval date
2026-06-14, 1405/03/24

Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1405.032

Health conditions studied

1

Description of health condition studied
Patients requiring buccal infiltration local anesthesia in the anterior maxillary region for dental procedures

ICD-10 code
R52

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Pain induced by local anesthesia injection.

Timepoint
Pain upon needle penetration (immediately after needle insertion into the mucosa and before anesthetic injection) and Pain during injection (immediately after completion of anesthetic solution injection).

Method of measurement
Pain intensity will be measured using the Visual Analog Scale (VAS).

Secondary outcomes

1

Description
Dental anxiety level
Timepoint
before the intervention
Method of measurement
Dental Anxiety Inventory (DAI) questionnaire

Intervention groups

1

Description
Intervention group: Participants will receive photobiomodulation using a 970-nm diode laser (Sirolaser Blue, Sirona Dental Systems GmbH, Germany) with a power output of 1.5 W in continuous-wave mode and an 800-µm fiber tip. Laser irradiation will be applied to the injection site for approximately 10–25 seconds. Standard buccal infiltration anesthesia will then be administered immediately.
Category
Treatment - Other

2

Description
Intervention group: A neutral gel without active ingredients will be applied to the injection site for one minute and subsequently removed. Sham laser application will then be performed using the same device appearance, sounds, aiming beam, duration, and positioning as active laser treatment, but without therapeutic energy emission. Standard buccal infiltration anesthesia will then be administered.
Category
Treatment - Other

3

Description
Intervention group: A neutral gel will be applied to the injection site for one minute. Active photobiomodulation with a 970-nm diode laser will then be delivered using the same parameters described for Group 1. The gel will subsequently be removed, and standard buccal infiltration anesthesia will be administered.
Category
Treatment - Other

4

Description
Control group: Participants will receive sham laser treatment without gel application, followed by standard buccal infiltration anesthesia.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Private dental clinic
Full name of responsible person
Nazanin Mohamadi
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Bustan 9th, Block 121, Ground Floor, Unit 4, Pasdaran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Sedigheh Al-Sadat Hashemi Kamangar, Vice Dean for Research, School of Dentistry
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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
Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nazanin Mohamadi

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available