Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of low-level laser on pain reduction during buccal and palatal infiltration anesthetic injections in maxillary teeth

Protocol summary

Study aim

General aim: determine the effect of low-level laser therapy (LLLT) on reducing pain during buccal and palatal local anesthetic infiltration in maxillary teeth. Specific aims: measure pain after (1) gel + laser + standard injection, (2) gel + standard injection, (3) laser + standard injection, (4) sham gel + sham laser + standard injection (control), and (5) compare pain across methods.

Design

A randomized, double-blind, controlled clinical trial with parallel groups. Block randomization was performed using statistical software.

Settings and conduct

The study is conducted outside the university on 72 patients in six groups of 12. A 970 nm diode laser is used at 1.5 W, continuous wave, for 10–25 seconds, with 20% benzocaine topical gel. Pain is assessed by VAS and pain difference (VAS.diff) between experimental and control sides. The pain score recorder, patient, and data analyzer are blinded.

Participants/Inclusion and exclusion criteria

Patients over 18 years, without dental pain or specific systemic conditions, requiring buccal or palatal local anesthetic injection for extraction or surgery on at least one side of the maxilla.

Intervention groups

Group 1: buccal laser. Group 2: palatal laser. Group 3: buccal topical anesthetic gel. Group 4: palatal topical anesthetic gel. Group 5: gel then buccal laser. Group 6: gel then palatal laser. Sham gel then sham laser was applied to the contralateral side as a control in all groups.

Main outcome variables

Injection pain is measured after the application of different pain reduction methods.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20261010071362N1**
Registration date: **2026-10-26, 1405/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-26, 1405/08/04**
Update count: **0**

Registration date

2026-10-26, 1405/08/04

Registrant information

Name

Nima Dehghani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-10-22, 1405/07/30

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low-level laser on pain reduction during buccal and palatal infiltration anesthetic injections in maxillary teeth

Public title
Effect of low-level laser on anesthetic injections pain reduction
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults over 18 years old Need for buccal or palatal infiltration injection for dental extraction and oral and dental surgeries Need for at least one treatment in each maxillary quadrant Individuals who signed the study consent form Patient must not have dental pain before the procedure
Exclusion criteria:
Allergy to the anesthetic agent and individuals with a contraindication to epinephrine Systemic disease and need for special treatment Local inflammation or any lesion at the injection Patient requiring emergency treatment for dental pain Contraindication to laser therapy, for example in individuals with a pacemaker
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **72**
More than 1 sample in each individual
Number of samples in each individual: **2**
This study was designed as a split-mouth study. In each group, one side of the maxilla is selected as the test side and the other side as the control side. Each individual reports two pain scores: control tooth pain (VAS) and test tooth pain (VAS).
Randomization (investigator's opinion)
Randomized
Randomization description
Using PASS 2026 statistical software and the block randomization option for a sample size of 72, with 6 study groups and a block size of 6, a randomization list is generated in which each row from 1 to 72 specifies a serial number, group, and type of intervention. On 72 papers, the serial number, group, and type of intervention are written according to the randomization list, and each paper is kept in a sealed envelope. After each patient enters the study, an envelope is allocated to them in the order of the randomization list, and the patient's name is written on it. These procedures are performed by someone who has no role in any stage of the study. To determine which side of the maxilla serves as the control and which side serves as the experimental side, a coin toss is also used, which is determined by the investigator performing the procedure before it is performed on the patient.
Blinding (investigator's opinion)
Double blinded
Blinding description
The sealed envelope for each patient, with the patient's name written on it, is opened by a restorative dentistry specialist, who performs the relevant intervention, of which the patient is unaware. Then, the anesthetic injection is administered by a sixth-year dental student who was not present in the room and enters after the intervention has been performed. The same person then records the patient's injection pain score on the envelope. The same process is also carried out on the tooth on the opposite side of the maxilla that requires treatment. After all samples have been collected, the data file is sent to the data analyst without the title of each group being revealed.
Placebo
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 Sciences
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TUMS School of Dentistry, North Kargar St., Tehran
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Tehran
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1439955991
Approval date
2026-02-07, 1404/11/18
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1404.104

Health conditions studied

1

Description of health condition studied
Control the pain of maxillary buccal and palatal infiltration anesthesia injection
ICD-10 code
G89.18
ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Injection pain intensity
Timepoint
Measurement of injection pain intensity immediately after injection
Method of measurement
Visual Analogue Scale for pain

Secondary outcomes

1

Description
.
Timepoint
.
Method of measurement
.

Intervention groups

1

Description
Intervention group:
Category
Treatment - Devices

2

Description
Intervention group:
Category
Treatment - Devices

3

Description
Intervention group:
Category
Treatment - Drugs

4

Description
Intervention group:
Category
Treatment - Drugs

5

Description
Intervention group:
Category
Treatment - Other

6

Description
Intervention group:
Category
Treatment - Other

7

Description
Control group:
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
Nima Dehghani
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Sponsors / Funding sources

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Tehran University of Medical Sciences
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
Persons

Person responsible for general inquiries

Contact
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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

gjk

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