

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Clinical assessment of laser application (Photobiomodulation) for reversal of soft-tissue local anesthesia in children

Protocol summary

Study aim

Determination of laser application in the removal of soft tissue local anesthesia in children

Design

split-mouth (each patient receives two treatments in each mandibular quadrant) double-blind randomized clinical trial

Settings and conduct

This study will be carried out in children ages 4 to 8 years old referred to the pediatric dentistry department of Tehran University of Medical Sciences. After the inclusion and exclusion criteria, patients will be randomly divided into two groups of treated with laser and without laser in two treatment sessions with an interval of 7 to 10 days (split- mouth). Patients' sensation of soft tissue will be evaluated and recorded every 15 minutes by palpation. The patient will also be evaluated for soft tissue trauma. clinical care, the outcome evaluator, researcher, patient and analyzer are blind at this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 4 - 8- year-old children who are able to understand and respond to soft tissue sensation
Requiring treatment by injection under anesthetic infiltration of mandibular primary first molar
Exclusion criteria: children with systemic conditions that prevent dental treatment under local anesthesia

Intervention groups

The intervention group will be exposed to diode laser radiation and in the control group, the laser when it's off is symbolically illuminated with the same distance and the same duration.

Main outcome variables

The reversal time for normal sensation of soft tissue and the incidence of soft-tissue trauma in the two intervention and control groups will be evaluated and compared

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180804040693N1**

Registration date: **2018-08-24, 1397/06/02**

Registration timing: **prospective**

Last update: **2019-01-08, 1397/10/18**

Update count: **1**

Registration date

2018-08-24, 1397/06/02

Registrant information

Name

Zahra Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical assessment of laser application (Photobiomodulation) for reversal of soft-tissue local anesthesia in children		Placebo Used Assignment Other Other design features
Public title The effect of laser on soft tissue anesthesia		Secondary Ids empty
Purpose Supportive		
Inclusion/Exclusion criteria Inclusion criteria: A child aged 4 to 8 years who is able to understand and respond to soft tissue sensation Complete the informed consent form by the parent or legal guardian of the patient Children who are ranked 3 or 4 on Frankl Rating Requiring treatment by injection under anesthetic infiltration of mandibular primary first molar Exclusion criteria: History of allergy to the substance of numbness and sulfite Receiving any pain medication at least 24 hours before treatment Any systemic conditions that prevent dental treatment under local anesthesia		Ethics committees 1 Ethics committee Name of ethics committee Ethics committee of tehran University of Medical Sciences Street address N Kargar, Tehran City Tehran Province Tehran Postal code 1439955991 Approval date 2018-07-21, 1397/04/30 Ethics committee reference number IR.TUMS.DENTISTRY.REC.1397.057
Age From 4 years old to 8 years old Gender Both Phase N/A Groups that have been masked - Participant - Care provider - Investigator - Outcome assessor - Data analyser		
Sample size Target sample size: 34 Randomization (investigator's opinion) Randomized Randomization description After reviewing the inclusion and exclusion criteria, each patient randomly using simple randomization and individual (open envelope sealed) divided into two groups of treated with laser and without laser in two treatment sessions with an interval of 7 to 10 days (split-mouth). There are 9 envelopes from each of the four modes (right with laser radiation, right without laser radiation, left with laser radiation, left without laser radiation). We ask a patient to choose an envelope from 36 envelopes and the envelope will be opened by the person responsible for the laser radiation at the same time. Blinding (investigator's opinion) Double blinded Blinding description For blind clinical care and the outcome evaluator and researcher, a separate person is responsible for laser radiation. So these people are blind at all stages of the laser radiation protocol. For blind the patient, at a meeting without laser treatment, the extinguishing laser appears symbolically with the same distance and the same duration of exposure. For blind analyzer, first analysis is done and then grouped into groups.		Health conditions studied 1 Description of health condition studied The effect of laser in reversing local anesthesia ICD-10 code Y48.3 ICD-10 code description Local anaesthetics (Adverse effect in therapeutic use)
Primary outcomes 1 Description Time of soft tissue local anesthesia Timepoint Assessment of sensation of soft tissue every 15 minutes Method of measurement Palpation with explorer in trained child		
Secondary outcomes 1 Description Trauma to soft tissue Timepoint At the end of the treatment and 24 hours later		

Method of measurement

Observation

Intervention groups**1****Description**

Intervention group: Laser therapy with an 810 nm wavelength laser diode (Fox, ARC laser Germany) with a 0.5 cm² cross-section handpiece with a density of 6 J / cm², a power of 200 mw, and an irradiation time of 15 seconds per continuous wave in soft tissue at the injection side (Infiltration point and anesthetized points on the lower lip)

Category

Treatment - Other

2**Description**

Control group: The Laser when it's off is symbolically illuminated with the same distance and the same duration

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran University of Medical Sciences Faculty of Dentistry

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Laser Research Center of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

Dr. Bahman Seraj

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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

Laser Research Center of Dentistry, 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

Zahra Hosseini

Position

Resident of Pediatric Dentistry

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

information about the main outcome

When the data will become available and for how long

Starting the access period from 1399

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

further research

From where data/document is obtainable

Email to z-hosseini@razi.tums.ac.ir

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

Explain the use of documentation that will be

Comments