

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of low_level laser(810 nm),Benzocaine anesthetic gel and pressure on reducing pain during infiltration injection

Protocol summary

Study aim

Comparison of low-power diode lasers (810 nm), gum massage (pressure), benzocaine anesthesia gel on pain during injection infiltration

Design

sham controlled clinical trial with a parallel group design: double blind

Settings and conduct

study will perform in endodontic department of Islamic Azad University of Tehran. 4 types of pre injection interventions will done while the volunteers and injection pain assessor are blinded.each of the four types of intervention is done for each person at intervals of one week.

Participants/Inclusion and exclusion criteria

Volunteers between 20 and 40 years with intact maxillary canine .Exclusion criteria:allergy to topical or local anesthetic agent,history of systemic disease, history of trauma in the side of injection:ulceration or inflammation of the buccal tissue: history of smoking:use of sedative or tranquilizer during the last 72 hours

Intervention groups

maxillary right canine area was prepared by laser radiation(diode laser 810nm) for12.5 second(energy density of 2 j/cm2, power 0.08 W). group2: 20% benzocaine topical anesthesia was applied for 2 min before injection. group3: pressure was applied to the anesthetized area with laser barrier in the silicone sheath for 2 min(as indicated by the observation of pale tissue).group4: control group followed by application of laser in the off mode and the placebo gel

Main outcome variables

Pain during injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141222020396N2**

Registration date: **2018-06-22, 1397/04/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-22, 1397/04/01**

Update count: **0**

Registration date

2018-06-22, 1397/04/01

Registrant information

Name

Mehdi Vatanpour

Name of organization / entity

Islamic Azad University.Dental Branch

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-10, 1397/03/20

Expected recruitment end date

2018-07-11, 1397/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low_level laser(810 nm),Benzocaine anesthetic gel and pressure on reducing pain during infiltration injection

Public title

The effect laser on reducing pain during injection

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

volunteers in the age between 20 and 40 years with intact maxillary canine, no need for dental treatment after confirming the consent form by the volunteers and informing about the drawbacks related to the interventions and the profit from participation, included the study

Exclusion criteria:

allergy to topical or local anesthetic agent history of systemic disease history of trauma in the injection area ulceration or inflammation of the buccal tissue history of smoking The use of sedative or tranquilizers during the last 72 hours

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **16**

More than 1 sample in each individual

Number of samples in each individual: **4**

4 types of pre injection interventions such as: Laser, Xylocaine gel, Pressure & Placebo

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization, sequential, sealed envelop. At the first session, the patient has four sealed envelopes containing four interventions that randomly select one and the selected envelope will be deleted at next sessions(1,2,3).

Blinding (investigator's opinion)

Double blinded

Blinding description

volunteers are blind because of the complete simulation of interventions(all interventions are implemented by the low probability laser probe).and the post injection pain assessor is blind because is different with the operator.

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Medical Science Branch, Islamic Azad university, Tehran

Street address

Neyestan 9th Alley, Pasdaran Street

City

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Province

Tehran

Postal code

19585175

Approval date

2017-09-24, 1396/07/02

Ethics committee reference number

IR.IAU.DENTAL.REC.1396,22

Health conditions studied**1****Description of health condition studied**

pain control

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

pain

Timepoint

Immediately after injection

Method of measurement

Visual Analogue scale

Secondary outcomes

empty

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

Intervention group: diode Laser 810 nm, power 0.08 W, Dose 2 J/cm² in 12.5seconds(Dental diode laser, navidAssayesh parsian, IRAN)

Category

Prevention

2**Description**

Intervention group: benzocaine 20% gel for 2 minutes

Category

Prevention

3

Description

Intervention group: Pressure for 2 minutes while the injection area tissue is pale

Category

Prevention

4

Description

Control group: placebo which all the previous interventions will simulated for volunteers.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad university Tehran Dental branch

Full name of responsible person

Mehdi Vatanpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Islamic Azad University

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

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mehdi Vatanpour

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person
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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

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

all the data of each volunteer can be provided after being unidentifiable.

When the data will become available and for how long

Starting 6 months after article publication

To whom data/document is available

All the volunteer can also apply to receive it.

Under which criteria data/document could be used

Any requested analysis is valid.

From where data/document is obtainable

Contact the person responsible for the study by email

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

Information will be available within 1 month of the request

Comments