Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Iran (Islamic Republic of)

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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 truma in the injection area ulceration or inflammation of the buccal tissue history of smoking The use of sedative or tranquillizers 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
Ethic committee of Medical Science Branch,Islamic Azad university, Tehran
Street address
Neyestan 9th Alley, Pasdaran Street
City
Tehran
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
Immediatlely 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: benzocaiene 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 Vatanpourt
Street address
9th Neyestan, pasdaran
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Zahra Habibi
Street address
Neyestan 9th Alley, Pasdaran street
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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
Dentistry
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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Zahra Habibi

Position

student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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