Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The effect of Prophylactic low level laser therapy on pain perception due to infiltration injection

Protocol summary

Study aim
Evaluation of the effect of 940 nm low power diode laser on pain reduction

Design
A clinical trial study with two parallel, single blind, randomized groups randomization technique: Covariate adaptive randomization with 30 patients.

Settings and conduct
This study will take place at Arak Dental School Clinic. Each patient will be treated by both techniques,topical lidocaine anesthesia gel with laser on one side and topical anesthesia gel alone in the other side.This protocol will be performed for the other half of the participants in reverse.Each patient will have different control and intervention sides the next session. On the control side,on the buccal mucosa of the maxillary canine , topical benzocaine anesthesia will be applied for one minute.Then a short needle (gauge 27) is used by the dentist for injection. On the test side,on buccal mucosa of the canine, anesthetic gel was applied for one minute and then laser irradiation at 940 nm was applied for one minute. Blindness: Patients are not aware of the type of anesthesia and on which side it will be performed.

Participants/Inclusion and exclusion criteria
The volunteers for performing bilateral maxillary canine anesthesia with a range of 20-27 years

Intervention groups
Maxillary canine anesthesia is performed bilaterally on one side with laser prophylaxis and on the other side without laser prophylaxis. In the other group, the same actions will be done in reverse order.

Main outcome variables
The outcome of both studies will be the degree of pain perception after the injection. Evaluation criteria for measuring pain in patients included: A) Physiological criteria of pain and stress B) Subjective pain criterion, which is the Faces Pain Rating Scale. C) Objective Pain Criterion (SEM). D) VAS (visual analogue scale)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200126046260N1**
Registration date: **2020-03-13, 1398/12/23**
Registration timing: **prospective**

Last update: **2020-03-13, 1398/12/23**
Update count: **0**

Registration date
2020-03-13, 1398/12/23

Registrant information

Name
Shakiba Zandi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Prophylactic low level laser therapy on pain perception due to infiltration injection

Public title
The effect of low level laser therapy on pain perception
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age between 20-27 years candidate for bilateral canine anesthesia
Exclusion criteria:
The patient has lost the canine tooth on one or both sides. The patient's age is outside the age range specified. The patient is taking painkillers or sedatives.
Age
From **20 years** old to **27 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **30**
More than 1 sample in each individual
Number of samples in each individual: **2**
bilateral pain perception
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is simple and individual. Randomization technique: covariate adaptive randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients are unaware of which side of the mouth is under laser prophylaxis.When using diode laser we also put the device in silent mode.The light is also not visible due to the direct contact of the laser probe with the mucosal surface.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
Street address
NO.39,Manoochehri St.,Esfahan
City
Arak
Province
Markazi
Postal code
8143764333
Approval date
2020-01-14, 1398/10/24
Ethics committee reference number
IR.ARAKMU.REC.1398.248

Health conditions studied

1

Description of health condition studied
The effect of laser therapy on injection pain
ICD-10 code
G89.1
ICD-10 code description
Acute pain, not elsewhere classified

Primary outcomes

1

Description
The amount of pain perception
Timepoint
5 seconds after starting the injection
Method of measurement
Visual Analog Scale -Faces Pain Rating Scale-Sound Eye motor pain-physiologic scale of pain and stress

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This study will be done by split mouth method. The purpose of split mouth study is to eliminate all variables related to different individuals. In Split Mouth method, buccal injection will be done on both sides of maxilla, so that injection will be done in two sessions separately, once in control side and once in test side. The priming of the injection and determination of the experimental and control side will be randomly selected by Covariate adaptive randomization. Both techniques are used for each patient, lidocaine local anesthetic gel with one laser and local anesthetic gel alone on the other. Half of the participants are randomly selected (Covariate adaptive randomization) to First apply the local anesthetic gel with the laser on one side and then the gel alone on the other side of their mouth. This protocol is performed for the other half of participants in reverse. On the control side, the buccal mucosa of the canine tooth is dried with a cotton roll for 30 seconds, then topical lidocaine anesthesia gel is

applied for one minute. Immediately using a powered off laser. used for 1 minute to create a placebo effect. On the test side, the buccal mucosa of the canine similar to anesthetic gel was applied for one minute and then laser irradiated at 940 nm before being injected for one minute.Then a short needle (gauge 27) is used by the dentist for injection. The injection will be done by ICT Injection. ICT Injection is a device that performs injection at a constant and adjustable speed and pressure. The device has three stages of injection, respectively, at speeds (1.8 ml / 250,150.50 s) and constant pressure. After preparation of the injection site, the device will be injected with the C-K Ject needle as follows: Initially 5 sec at 1.8 ml / 250 s in stage 1, then 5 sec at 1.8 ml / 150 s in stage 2 and in the remaining carpal anesthesia at 1.8 ml / 50 s in stage 3. Be.Patients in this study will be anesthetized with 2% Lidocaine plus Lidocaine 1% 8000 2% E-80, Darou Pakhsh, Karaj, Iran).

Category

Treatment - Devices

2

Description

Control group: At the control side, the buccal mucosa of the canine tooth is dried with cotton roll for 30 seconds, then topical lidocaine anesthesia gel is applied for one minute. This process is immediately followed by silent laser application for 1 minute to produce a placebo effect and then The injection is done in the same way.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Arak Dental School

Full name of responsible person

Shakiba Zandi

Street address

Arak Dental School-Alghadir Blvd_Basij Sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Shakiba Zandi

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 potential data is shared after unidentifying patients.
When the data will become available and for how long
Start of access period 6 months after printing results.
To whom data/document is available
Data and other documentation will be available to researchers and other prospective data seekers.
Under which criteria data/document could be used
All scientific and practical uses of this data are permitted.
From where data/document is obtainable
via E-mail: zandi9574@gmail.com
What processes are involved for a request to access data/document
You will receive a reply within a week after the request is sent to the above email.
Comments