Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of low-level laser therapy on pain reduction of anterior maxillary infiltration injection

Protocol summary

Study aim
Investigating the effect of low-level laser therapy on pain reduction of anterior maxillary infiltration injection

Design
Clinical trials with cross over, triple blind, randomized groups

Settings and conduct
For each person, two infiltration Injections will be performed in two weeks intervals on both sides of the anterior maxilla (On one side, the control and on the other, the intervention will be carried out). Before starting, the patients are provided with two set envelopes which identifies the control or the intervention in the first turn and in the next turn, the reverse will be carried out. After the selection of the envelope by the patient, the first administer will adjust the device according to the envelope chosen by the patient. Then, the second administrator will apply the low-level laser for 90 seconds without being informed of the device's setting and immediately the 4% lidocaine (epinephrine 1:100000) will be injected. Afterwards, the patient will determine the pain intensity according to the visual analogue scale. This study has been designed in three ways and the participant, the injector and the data analysts would be unaware of the radiation or inactivation of the laser before injection.

Participants/Inclusion and exclusion criteria
Inclusion criteria: General health, Absence of pathologic lesion at the injection site, Age range from 20 to 25 years, In need of restoration or root treatment. Exclusion criteria: Allergy to Lidocaine injectable drug, Use of any sedative and anti-depression drugs in two weeks period.

Intervention groups
Intervention group: laser radiation with power of 100 mw, then infiltration injection in maxilla with lidocaine 4% solution with epinephrine 1:100000. control group: laser radiation with power of 0 mw, then infiltration injection in maxilla with lidocaine 4% solution with epinephrine 1:100000

Main outcome variables
Intensity of injection pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20140527017880N7**
Registration date: **2018-11-08, 1397/08/17**
Registration timing: **retrospective**

Last update: **2018-11-08, 1397/08/17**
Update count: **0**

Registration date
2018-11-08, 1397/08/17

Registrant information
Name
Roohollah Sharifi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-07-10, 1397/04/19
Expected recruitment end date
2018-08-10, 1397/05/19
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of low-level laser therapy on pain reduction of anterior maxillary infiltration injection

Public title

Determining the effect of low-level laser therapy on reducing the injection pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

General health Absence of pathologic lesion at the injection site Age range from 20 to 25 years In need of restoration or root treatment

Exclusion criteria:

Allergy to Lidocaine injectable drug Use of any sedative and anti-depression drugs in two weeks period

Age

From **20 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is a simple method meaning that the selected units have the equal chance of been chosen. Random unit is of individual type and choosing and random instruments are selected envelopes for which the selection process can be carried out by lottery or by person. In this way, the patients are provided with two sets of envelopes. One set includes 84 envelopes: 42 A and 42 B (A: right and B: left) and the other set includes 84 envelopes: 42 C and 42 D (C: intervention side and D: Control side) and then each patient by choosing two envelopes from each set will determine the intervention or control side in the first run and at the next run the reverse is carried out.

Blinding (investigator's opinion)

Triple blinded

Blinding description

First, the patient chooses one of the C or D envelopes (C: laser radiation with power of 100 mw, D: laser radiation with power of 0 mw as placebo), then the first executor adjusts the laser device according to the patient-selected envelope, and eventually the second executor adjusts the low-level laser without noticing the patient's choice and immediately does the injection. Then, the patient determines the pain intensity by the use of the visual analog index, and then the analyst analyzes the information without knowing the codes. Blinding is done only by one of the researchers. Therefore, the patient, the injector and the analyst won't find out whether the laser has been radiated or not.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Ethics Committee, Vice Chancellor for Research and Technology, Building No.2, Kermanshah University of Medical Sciences, Shahid Beheshti Boulverd

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Postal code

6714673159

Approval date

2018-08-15, 1397/05/24

Ethics committee reference number

IR.KUMS.REC.1397.348

Health conditions studied

1

Description of health condition studied

Local anesthesia

ICD-10 code

Y48.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Pain intensity of infiltration injection

Timepoint

Immediately after injection

Method of measurement

Based on the Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: first laser with power of 100 mw is radiated. The characteristics of the laser are as follow: low-level laser from Quick Laser with simultaneous radiations (810 and 980 nm), power of 12 w, manufactured by England Quick Laser Company, with the energy of 4 j/cm2 and cross section of 225 mm2 that is applied to the mucous membrane in a vertical form throughout the method of contact with no pressure texture in 90 seconds by a dentist. Then immediately, a 4% lidocaine carpool (epinephrine 1:100000, Iran Daroo Pakhsh) will be injected. All the injections will be carried out under the same circumstances in the depth of vestibule and adjacent to the root of maxillary's central tooth by a dentist (The bull of the needle's point should be toward the bone, the needle should be short 27 and the depth of needle penetration should be 2-4 mm and the time of carpool evacuation should be 1 minute).

Category
Treatment - Devices

2

Description
Control group: first laser with power of 0 mw is radiated as plascebo. The characteristics of the laser are as follow: low-level laser from Quick Laser with simultaneous radiations (810 and 980 nm), power of 12 w, manufactured by England Quick Laser Company, with the energy of 4 j/cm2 and cross section of 225 mm2 that is applied to the mucous membrane in a vertical form throughout the method of contact with no pressure texture in 90 seconds by a dentist. Then immediately, a 4% lidocaine carpool (epinephrine 1:100000, Iran Daroo Pakhsh) will be injected. All the injections will be carried out under the same circumstances in the depth of vestibule and adjacent to the root of maxillary's central tooth by a dentist (The bull of the needle's point should be toward the bone, the needle should be short 27 and the depth of needle penetration should be 2-4 mm and the time of carpool evacuation should be 1 minute).

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Department of Restorative, School of Dentistry, Kermanshah University of Medial Sciences.

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
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Position
Dental student

Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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