Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of low power laser in reducing the pain of mandibular block injection in restorative patients

Protocol summary

Study aim
Evaluation of the effect of low power laser in reducing the pain of mandibular block injection

Design
A clinical trial with a control group, with a parallel, double-blind, randomized group, on 59 patients, the RANDBETWEEN command of Excel software was used for randomization.

Settings and conduct
For each patient, two injections of the alveolar block in the posterior area of both sides of the mandible will be performed twice in two weeks at the dental school. In the first session, for all patients, mandibular molar restoration is performed on the right side. For this purpose, using a table of random numbers, people are divided into two groups: laser and placebo. In the second session, restoration is performed on the left tooth and the methods are changed in such a way that patients who received a laser in the first session receive a placebo on the left side and patients who received a placebo receive a placebo this time on the left side. Left receive the laser. The patient and the outcome assessor will be blind during the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: general health, insensitivity to lidocaine injection, no painkillers, anesthesia, sedation and antidepressant for two weeks, no pregnancy
Exclusion criteria include: non-cooperation, sensitivity to injectable drug, more than one injection per person, withdrawal of participants

Intervention groups
The intervention involves the use of a low-power laser before the injection, in the intervention group the laser is irradiated and then the injection is performed.

Main outcome variables
Measurement of pain during injection of mandibular alveolar nerve block

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220227054137N1**
Registration date: **2022-03-15, 1400/12/24**
Registration timing: **retrospective**

Last update: **2022-03-15, 1400/12/24**
Update count: **0**

Registration date
2022-03-15, 1400/12/24

Registrant information

Name
Elahe Vlaee
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-23, 1400/12/04

Expected recruitment end date
2022-03-15, 1400/12/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the effect of low power laser in reducing the pain of mandibular block injection in restorative patients

Public title

Evaluation of the effect of low power laser in reducing injection pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

General health Insensitivity to lidocaine injection No use of any analgesics, anesthesia, sedation and antidepressant for two weeks No pregnancy

Exclusion criteria:

Lack of cooperation Sensitivity to the injectable drug If for any reason during the intervention more than one injection is applied for each person Cancellation of the participants Very high and low pain threshold

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **59**

More than 1 sample in each individual

Number of samples in each individual: **2**

Given that two injections are given for each person, each person will give us two samples to compare the effect of the laser in reducing pain.

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done only in the first session in a simple and individual way. A table of random numbers is used for randomization. In Excel software environment, four-digit codes are generated using the RANDBETWEEN command. Each patient is assigned a 4-digit code that if the end digit to the right of the code is 1, 2, 5, 7, 9, at the first visit, they will be given laser radiation, and if the end digit of the code is 0, 3, 4, 6, 8 In the second visit, laser radiation is performed for them. All codes are recorded on paper and stored in specific envelopes. The envelopes are arranged randomly and the responsible secretary, who is aware of the objectives of the study, will give them one of these envelopes before entering the doctor's room when reviewing the inclusion criteria and recording patient information.The secretary is not aware of the study hypothesis and is not aware of the details of the codes for assigning to groups. The doctor will decide on the treatment process for the patient based on the specified code.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed in two forms. Patients are not exposed to the laser radiation. For this purpose, when the laser is not irradiated, the device is still on, which makes the patient unaware of whether the device is on or not by making a sound. Also, the outcome assessor is not in the process of allocating patients. Therefore, they are also unaware of how to allocate.

Placebo

Used

Assignment

Parallel

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

Boostan dormitory , zakaria Razi Blv

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Postal code

7461168617

Approval date

2022-02-23, 1400/12/04

Ethics committee reference number

IR.KUMS.REC.1400.800

Health conditions studied

1

Description of health condition studied

Evaluation of the effect of low power laser in reducing the pain of mandibular block injection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measurement of pain during injection of mandibular alveolar nerve block

Timepoint

Start of study and 14 days after intervention

Method of measurement

The method of measuring pain intensity is the use of a visual analog scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For each patient, two injections of alveolar block in the posterior area of both sides of the mandible will be performed twice in two weeks. In the first session, for all patients, mandibular molar restoration is performed on the right side. For this purpose, using a table of random numbers, people are divided into two groups: laser and placebo. In the second session, restoration is performed on the left tooth and the methods are changed in such a way that patients who received a laser in the first session receive a placebo on the left side and patients who received a placebo receive a placebo this time on the left side. Left receive the laser. The interval between the first and second session is at least two weeks. The patient opens his mouth wide.We see a mucosal protrusion from almost behind the upper tuberosity, which extends to the back of the lower 7 tooth and is called the trigomandibular ridge. Near the trigeminal raphe is where the needle enters the corner of the mouth and about 2 cm of the needle is inserted to hit the bone. In the control group, the device is on, but the laser is not emitted. In fact, the patient is not aware that the laser is on or off and hears the false sound of the device.Settings of low power laser device with specifications: low power laser, quick lase 810nm + 980nm, 12w Dual cw (manufactured by Quick Liz UK, energy 0.3 joules, time s240, cross section 225 mm2, by contact method without pressure Apply perpendicular to the contact area by the first performer and immediately inject a 4% carpol lidocaine (epinephrine 1: 100000).

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kermanshah School of Dentistry

Full name of responsible person

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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

Kermanshah University of Medical Sciences

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Zohreh Rahimi

Position

University Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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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
Not applicable
Data Dictionary
Not applicable