

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jun 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)

##### Phone

+98 919 815 6954

##### Email address

elahev9@gmail.com

##### 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

###### **City**

Kermanshah

###### **Province**

Kermanshah

###### **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

Elahe vlaee

##### Street address

Boostan Dormitory , Zakaria Razi Blv

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

7461168617

##### Phone

+98 83 3428 1374

##### Email

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Full name of responsible person

Zohreh Rahimi

##### Street address

Kermanshah, Daneshgah St., School of Medicine, Vice Chancellor for Research and Technology

##### City

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##### Province

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##### Postal code

6715847141

##### Phone

+98 83 3427 4621

##### Email

zrahimi@kums.ac.ir

#### 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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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Elahee vlaee  
**Position**  
Dental Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
Dentistry  
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## Person responsible for updating data

### 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

Not applicable

### Data Dictionary

Not applicable