

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Investigating the effect of low level diode laser on the pain caused by local anesthesia in dentistry

#### Protocol summary

##### Study aim

Investigating the effect of low power diode laser on pain caused by local anesthetic injection in dentistry

##### Design

The clinical trial has a control group with single and double-blind randomized groups with a sample size of 30 patients. A table of random numbers will be used for randomization

##### Settings and conduct

The studied patients will include 30 people who refer to a private practice. After the patients enter the study, the trained assistant of the clinic, based on the table of random numbers, determines and records which side of the upper jaw (left or right) the laser or sham laser will be irradiated. Then the dentist places the laser handpiece on the left and right side of the patient's maxilla and performs the radiation. Dentist and patient do not know on which side the laser is irradiated and on which side the sham laser is irradiated. After irradiation on each side in the irradiation site, anesthesia will be injected into the maxilla with a 25 mm needle and gauge number 27 in the amount of 3.4 carpoles. took Immediately after the injection of anesthesia on each side, the amount of pain and burning caused by the injection will be measured using the VAS scale.

##### Participants/Inclusion and exclusion criteria

Age over 18 years, having anterior teeth on both sides in the upper jaw, and the need for dental procedures that require injecting anesthesia on both sides, and the absence of pain and infection in the area

##### Intervention groups

Diode laser with a wavelength of 980 nm manufactured by Dr.smile company in Italy will be used. The parameters of the laser include a power of 300 milliwatts (0.3 watts), an irradiation time of 20 seconds, and an energy density of 6 joules per square centimeter

##### Main outcome variables

amount of pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20231209060303N1**

Registration date: **2024-01-09, 1402/10/19**

Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**

Update count: **0**

##### Registration date

2024-01-09, 1402/10/19

##### Registrant information

##### Name

Ehsan babaei-zarch

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3521 3641

##### Email address

e.babaeizarch@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-01-10, 1402/10/20

##### Expected recruitment end date

2024-02-09, 1402/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of low level diode laser on the pain caused by local anesthesia in dentistry

#### Public title

Investigating the effect of low level diode laser on the pain caused by local anesthesia in dentistry

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age over 18 years Having front teeth on both sides in the upper jaw The need for dental procedures will include restoration, root canal treatment and tooth extraction, which will require the injection of infiltrated anesthesia on both sides Absence of pain and infection of the area

##### Exclusion criteria:

People whose age is too young (under 18) or too old and the information obtained from them is not reliable Infectiousness of the injection site People who are allergic to anesthetic drugs Toothless people in the tested areas

#### Age

From **18 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

- Participant
- Investigator

#### Sample size

Target sample size: **30**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The randomization method in this experiment is simple and the randomization unit will be individual. In this way, the trained clinical assistant will determine by random number table which side of the jaw (left or right) each person will be lasered on and on which side the laser will be turned off. The patient and the dentist will not know which side of the laser. And they don't know which side of the off laser was irradiated, and only a trained assistant who is aware of random numbers will perform the irradiation and collect the information in a checklist.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

The dentist and the patient do not know which side of the laser and which side of the sham laser or silent laser is irradiated because both types of lasers have the same light and sound, and both sides of the front of the patient's upper jaw require dental procedures that require It infiltrates numbness

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Yazd Faculty of Dentistry

##### Street address

Yazd Dahe fajr Boulevard. Yazd Faculty of Dentistry

##### City

Yazd

##### Province

Yazd

##### Postal code

8914815667

#### Approval date

2023-12-16, 1402/09/25

#### Ethics committee reference number

IR.SSU.DENTISTRY.REC.1402.061

## Health conditions studied

### 1

#### Description of health condition studied

Comparing the effect of laser with placebo in reducing pain caused by anesthetic injection

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

The amount of pain and burning caused by the injection is measured using the VAS scale. The VAS measure is a ten-centimeter segment numbered from 0 to 10. The number zero indicates no pain (there is no pain) and the number 10 means the most pain that the patient has experienced during his life.

#### Timepoint

Immediately after injection of anesthesia

#### Method of measurement

VAS criterion

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Diode laser with a wavelength of 980 nm manufactured by Dr.smile company in Italy will be used. The cross-section of the handpiece is in the form of

a circle with an area of one square centimeter, which is in contact with the mucosa without putting pressure on it. The parameters of the laser include a power of 300 milliwatts (0.3 watts), an irradiation time of 20 seconds, and an energy density of 6 joules per square centimeter

**Category**

Other

**2****Description**

Control group: using a laser device; A sham laser, which has the same light, sound and appearance as a low-power diode laser, will be emitted

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Private clinic

**Full name of responsible person**

Ehsan Babaei zarch

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Hana Alley ; Taleghani Street

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Yazd

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Amin Salehi

**Street address**

Fajr decade Blvd. Dental college

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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**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Ehsan Babaei zarch

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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Tenth Fajr Faculty of Dentistry Boulevard

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Ehsan Babaei zarch

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Yazd University of Medical Sciences  
**Full name of responsible person**  
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**Position**  
Assistant professor  
**Latest degree**  
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**Other areas of specialty/work**  
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**Province**  
Yazd  
**Postal code**

## 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