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 carpools. 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)

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+98 35 3521 3641

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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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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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Person responsible for scientific inquiries

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Person responsible for updating data

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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