

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the efficacy of 810 nm low power diode laser in reducing pain caused by anesthetic injection in dental treatments by the doctor of the restorative department of Zanjan Dental School.

Protocol summary

Study aim

Assessing pain levels resulting from anesthesia injection in dental patients within the control group. Evaluating pain levels resulting from anesthesia injection in dental patients undergoing treatment with 810 nm low power diode laser. Comparing the pain experience between the control group and patients receiving 810 nm low power diode laser treatment during dental anesthesia injections.

Design

Randomization was done based on block randomization methods with a volume of 4 (blocked randomization was for the purpose of making sure that exactly equal number of participants entered the intervention and control groups at consecutive but equal time intervals). First, the samples were entered into the study, then they were assigned to two groups using random blocks with a volume of 4 people. The order of the blocks and also the order of the groups within the blocks were random. The blocks were prepared using R software and provided to the therapist. In the present study, block randomization was used to allocate people to intervention groups

Settings and conduct

Zanjan University of Medical Sciences

Participants/Inclusion and exclusion criteria

1. Patients in the age group over 12 2. Patients who were willing to participate in the study while having informed written consent. 3. Patients who needed repair and therefore anesthesia injection. 4. Absence of inflammation or local sensitivity at the injection site 5. Being healthy No entry: patients with severe anxiety

Intervention groups

People receiving low power laser

Main outcome variables

Pain level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230619058531N1**

Registration date: **2024-02-19, 1402/11/30**

Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**

Update count: **0**

Registration date

2024-02-19, 1402/11/30

Registrant information

Name

Alireza Ganjkhanlo

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3347 0219

Email address

alirezakhanloznj@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-04, 1402/12/14

Expected recruitment end date

2024-04-02, 1403/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the efficacy of 810 nm low power diode laser in reducing pain caused by anesthetic injection in dental treatments by the doctor of the restorative department of Zanjan Dental School.

Public title

Investigating the efficacy of 810 nm low power diode laser in reducing pain caused by anesthetic injection in dental treatments by the doctor of the restorative department of Zanjan Dental School.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who need repair and therefore anesthesia injection. Patients with caries

Exclusion criteria:

Patients with severe anxiety

Age

From **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In the current study, the blocking method will be used to balance the number of samples assigned to each of the studied groups. The size of the blocks will be chosen randomly. A block size of 4 will be calculated and determined for this study. Subsequently, a randomization list will be generated to specify the treatment allocation for each participant within each block. As participants are enrolled in the study, they will be assigned to the next treatment group based on the randomization list within the corresponding block.

Blinding (investigator's opinion)

Single blinded

Blinding description

The researcher herself knows about laser radiation or non-radiation, but patients do not know about laser radiation or non-radiation due to lack of knowledge about laser function.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the University of Medical Sciences

Street address

Zanjan, at the end of Mahdavi Boulevard, Zanjan University of Medical Sciences, Faculty of Dentistry

City

Zanjan

Province

Zanjan

Postal code

4513956184

Approval date

2023-06-06, 1402/03/16

Ethics committee reference number

IR.ZUMS.REC.1402.073

Health conditions studied

1

Description of health condition studied

Dental caries, Pain , Stress

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Pain intensity based on Visual Analogue Scale

Timepoint

1 day after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Control: Receiving local anesthesia, which includes 2% lidocaine anesthetic, which is injected as an infiltrate.

Category

Placebo

2

Description

Intervention group: The laser receiver is irradiated by an

elexxion brand device with a wavelength of 810 nm and a power of 0.5 watts, which is directly irradiated for 15 seconds before injecting the anesthetic at the injection site.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Zanjan Medical Science School

Full name of responsible person

Alireza Ganjkanlo

Street address

Faculty of Dentistry, Zanjan University of Medical Sciences, at the end of Mahdavi St., Zanjan

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alirezakhanloznj@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samad Nadri

Street address

Zanjan University of Medical Sciences Vice President of Research and Technology, Azadi Square, Azadi Blvd, Zanjan, .,

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Grant name

Dental student thesis grant

Grant code / Reference number

5222

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan 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

Zanjan University of Medical Sciences

Full name of responsible person

Alireza Ganjkanlo

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Name of organization / entity

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Student

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Person responsible for updating data

Contact

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is accessible

When the data will become available and for how long

From 2025

To whom data/document is available

Students

Under which criteria data/document could be used

Scientific uses and completely free

From where data/document is obtainable

Zanjan University of Medical Sciences

What processes are involved for a request to access data/document

By email

Comments