

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of root canal disinfection by 980nm Diode laser on post operative pain after single visit root canal treatment of first and second maxillary molars: A randomized clinical trial

Protocol summary

Study aim

Evaluation of the effect of root canal disinfection by 980 Nanometre (nm) diode laser on post-operative pain after single visit root canal endodontic treatment of the maxillary molar with pulp necrosis

Design

The clinical trial will be performed with case and control groups with parallel groups, one-way blind, randomized by balanced block and 27 patients (totally 54 patients) in each group.

Settings and conduct

The study is committed in the endodontics department of the Faculty of dentistry, Azad University of Tehran. After Anesthesia, Isolation is accomplished with rubber dam. After access cavity preparation and determination of working length, the rotary motor will be used for filling the canals. Irrigation by sodium hypochlorite 5.25 percent will be done. Apical enlargement to size F3 will be done. Then canals will be dried by paper points. Then the patients will be placed in laser and control groups. Obturation will be performed by lateral condensation technique. The patient's pain will be recorded by Visual Analogue Scale immediately after the treatment, 4, 12, 24, 48, 72 hours and then 7 days after the treatment.

Participants/Inclusion and exclusion criteria

patients must have pulp necrosis of maxillary molar and must be between 18 to 50 year old. Non-entry criteria included teeth that have already undergone endodontic treatment, patients taking analgesia 12 hours before the intervention or who have taken antibiotics in previous month, and patients who have acute pain at the time of intervention.

Intervention groups

Laser : After preparation of the canal, the laser radiation will be performed by a 980 nm diode laser in the root canal. Control: Similar to the laser group, tips will be inserted into the canal but won't be activated and the

steps will be simulated

Main outcome variables

Post operative pain after Endodontic treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220607055098N1**

Registration date: **2022-08-16, 1401/05/25**

Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**

Update count: **0**

Registration date

2022-08-16, 1401/05/25

Registrant information

Name

Saba Rai

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8857 7243

Email address

sabarai12@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-06, 1401/06/15

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of root canal disinfection by 980nm Diode laser on post operative pain after single visit root canal treatment of first and second maxillary molars: A randomized clinical trial

Public title

Effect of root canal disinfection by 980nm Diode laser on post operative pain after single visit root canal treatment of first and second maxillary molars

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

All the patients must have pulp necrosis of maxillary molar. Patients must be between 18 to 50 years old.

Exclusion criteria:

Patients who have taken antibiotics in the month before the intervention. Patients taking analgesia 12 hours before the intervention. Teeth that have already undergone endodontic treatment. Patients who have acute pain at the time of intervention.

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method is balanced block. The randomization unit of each molar tooth belongs to each single patient and only one molar tooth from each patient is included in the study. The randomization tool uses a table of printed random numbers, the odd digit of group A and the even digit of group B until the intervention in the block is filled, and then the results are recorded in the order of registration and allocation of each sample inside the sealed envelope, which at the time of the intervention The envelope will be opened. The way to make a random sequence is based on the sequence of people's referrals. The person who determines the type of random allocation of samples is the consultant of methodology and statistics of the study, who leaves the sealed envelopes at the disposal of the clinical researcher and has no role in the clinical research process. The envelopes remain sealed until the intervention and are opened in the order mentioned on the back of the envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

The steps of both groups are the same. In both the laser and placebo groups, the tips will be inserted into the canal to the working length, but in the placebo group the lasers will not be activated and only the disinfection steps by laser will be simulated. Before the operation, the two groups will be explained to the patients and all the patients will be told that you are not aware of the treatment group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

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No. 9, 9th Neyestan, Pasdaran Avenue

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Province

Tehran

Postal code

1946853314

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.IAU.DENTAL.REC.1400.169

Health conditions studied**1****Description of health condition studied**

نکروز پالپی

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

Primary outcomes**1****Description**

Pain after endodontic treatment

Timepoint

Immediately after treatment, 4 hours, 12 hours, 24 hours, 48 hours, 72 hours and 7 days after treatment

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Laser : After preparation of the canal, the laser radiation will be performed by a 980 nm diode laser in the root canal. Irradiation will be performed in 4 pulses, each pulse is laser radiation for 5 seconds and then stops for 10 seconds. The movement speed of the tip is 2 mm/s and the location of the tip is 1 mm above the apex. It will be performed with a power of 1.2 watts, and the tips with a diameter of 200 microns and a length of 15 mm go into the canal until the working length, and the laser is irradiated by rotation and then exits the channel.

Category

Treatment - Devices

2

Description

Control group: Similar to the laser group, tips will be inserted into the canal but won't be activated and the steps will be simulated.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontics department of Faculty of Dentistry,
Islamic Azad University of medical sciences

Full name of responsible person

Mahta Falyab

Street address

No. 9, 9th Neyestan, Pasdaran Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Saba Rai

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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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

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

Yes - There is 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

Not applicable

Title and more details about the data/document

All potential data can be shared after the participants are unidentifiable.

When the data will become available and for how long

Access period starts from 2024.

To whom data/document is available

Only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The data can be used for scientific researches.

From where data/document is obtainable

Saba Rai Sabarai12@gmail.com

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

After submitting the request, the request will be reviewed and answered as soon as possible.

Comments