

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effect of low level laser therapy with 980 nm diode on post endodontic pain after single-visit retreatment in mandibular molars with periapical lesion

Protocol summary

Study aim

The aim of this study is to determine the effect of 980 nm low-power laser on postoperative pain after a single-visit endodontic retreatment in mandibular molar teeth with periapical lesion in patients referred to an endodontic specialized clinic.

Design

This will be a randomized triple blind clinical trial.

Settings and conduct

This will be a randomized triple blind clinical trial. The research is going to take place in Department of endodontics, Faculty of dentistry, Tehran medical sciences, Islamic Azad University, Tehran, Iran.

Participants/Inclusion and exclusion criteria

Patients included in this study were scheduled for RCR on mandibular molars, presented with periapical lesions with scores 2 or 3 in accordance with the periapical index classification introduced by Ørstavik et al, and had a pain VAS <56 and a percussion pain VAS <56. All patients were in good health as determined by health history and verbal questioning. Periodontal probing greater than 3 mm, swelling or sinus tract, and palpation and percussion VAS>56 are the exclusion criterias. Besides, all the teeth that have been diagnosed to be unrestorable after the endodontic retreatment in the primary evaluations, will be excluded from the study.

Intervention groups

Intervention Group: 980 nm low level laser Control
Group: Placebo

Main outcome variables

Prevention of post endodontic retreatment pain.

General information

Reason for update

Acronym

LLLT

IRCT registration information

IRCT registration number: **IRCT20110212005804N5**

Registration date: **2019-10-20, 1398/07/28**

Registration timing: **retrospective**

Last update: **2019-10-20, 1398/07/28**

Update count: **0**

Registration date

2019-10-20, 1398/07/28

Registrant information

Name

Mahta Fazlyab

Name of organization / entity

Islamic Azad University, Dental Branch, Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

mfazlyab@dentiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-02, 1397/11/13

Expected recruitment end date

2019-09-22, 1398/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of low level laser therapy with 980 nm diode on

post endodontic pain after single-visit retreatment in mandibular molars with periapical lesion

Public title

Low level laser therapy and post endodontic pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients included in this study were in need of RCR on mandibular molars. They were presented with periapical lesions with scores 2 or 3 in accordance with the periapical index classification introduced by Ørstavik et al. A pain VAS <56. A percussion pain VAS <56. All patients were in good health as determined by health history and verbal questioning.

Exclusion criteria:

Periodontal probing greater than 3 mm. Swelling or sinus tract. Palpation and percussion VAS >56. All the teeth that have been diagnosed to be unrestorable after the endodontic retreatment in the primary evaluations, will be excluded from the study.

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **18**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are placed in a randomized 4-block by the method of Balanced block. The randomization process is performed by an individual other than the investigator, and the information about the sample intervention is stored in sealed envelopes in order to randomize in excel software. The envelopes contain 18 items for the case group and 18 for the control group. Patients are divided into two groups according to their age and sex.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The patient is not aware of the research process. The investigator is not aware of the research process. The evaluator is not aware of the research process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Faculty of Dentistry, Islamic Azad University

Street address

No. 9, Faculty of Dentistry Islamic Azad University, 9th Neyestan Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2018-12-22, 1397/10/01

Ethics committee reference number

IR.IAU.DENTAL.REC.1397.028

Health conditions studied

1

Description of health condition studied

Post Endodontic Retreatment pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

post endodontic retreatment pain

Timepoint

4, 8, 12, 24, 48, 72 hours and day 7

Method of measurement

VAS ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 980nm low level laser

Category

Prevention

2

Description

Control group: placebo laser

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of endodontics, Faculty of dentistry,
Tehran medical sciences, Islamic Azad University, T

Full name of responsible person

Dr Mahta Fazlyab

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No.9, Neyestan 9 Ave, Pasdaran Ave

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dr.mfazlyab@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Arash Azizi

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No.9, 9th Neyestan Ave, Pasdaran Ave

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

None applicable

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**

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Mahta Fazlyab

Position

Assistant Professor of Endodontics department,
Faculty of Dentistry of Islamic Azad University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Title and more details about the data/document

A part of the information, such as information on the main outcome, can be shared

When the data will become available and for how long

The start of the access period will be 6 to 12 months after the results are released

To whom data/document is available

Data will only be available to researchers working in academic institutions

Under which criteria data/document could be used

Data will be available for dental research centers, universities and public and private health centers. All clinicians using laser to reduce pain after endodontic retreatment are allowed to use the documentation. Dr. Mahta Fazlyab dr.mfazlyab@gmail.com +982122564571 No. 9, Faculty of Dentistry Islamic Azad University, 9th Neyestan Ave, Pasdaran Ave.

From where data/document is obtainable

Applicants can contact the person responsible for the article to receive the information. Dr.Mahta Fazlyab dr.mfazlyab@yahoo.com Faculty of dentistry of Islamic Azad university +982122564571 No. 9, Faculty of Dentistry Islamic Azad University, 9th Neyestan Ave, Pasdaran Ave.

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

Demand by email to the person responsible for the article Dr.Mahta Fazlyab dr.mfazlyab@yahoo.com

Comments