

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

**Street address**

No.9, Neyetan 9 Ave, Pasdaran Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

**Phone**

+98 21 2256 4571

**Email**

dr.mfazlyab@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr Arash Azizi

**Street address**

No.9, 9th Neyestan Ave, Pasdaran Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1946853314

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**Email**

dr.mfazlyab@gmail.com

**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 scientific inquiries

### Contact

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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**