

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effect of low level laser therapy with 980 nm diode on post endodontic pain after single-visit treatment of necrotic mandibular molars with periapical lesion; A randomized clinical trial

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 treatment in necrotic mandibular molar teeth with periapical lesion in patients referred college of Dentistry, Islamic Azad University of Tehran in 1399-1400

Design

This will be a randomized triple blind clinical trial.

Settings and conduct

This triple blind clinical trial with randomized allocation is held in Department of Endodontics, Faculty of dentistry, Islamic Azad University, Tehran. The randomization process is performed by the investigator, and the information about the sample intervention is stored in sealed envelopes. Care provider (endodontist) and investigator (dental student) are aware of the group allocation and process. After treatment in intervention group low level laser therapy and in control group no laser will be applied and the effect on post endodontic pain will be evaluated.

Participants/Inclusion and exclusion criteria

Patients included in this study were those in need for root canal treatment on mandibular molars with pulp necrosis diagnosed with vitality tests and with periapical lesions scoring 2 or 3 in accordance with the periapical index classification introduced by Ørstavik et al, they had no pain with pulpal origin and had pain on percussion with VAS > 56. Patients in good health and systemic condition determined by health history and verbal questioning were included. Exclusion criteria were periodontal probing depth greater than 3 mm, swelling or presence of sinus tract, patients taking analgesia 12 hours prior to intervention, teeth with open apices (immature or inflammatory root resorption) and teeth diagnosed to be non-restorable after the endodontic treatment in primary evaluations.

Intervention groups

Intervention Group: 980 nm low level laser control group: no laser (placebo)

Main outcome variables

post-treatment pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110212005804N7**

Registration date: **2020-10-28, 1399/08/07**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-28, 1399/08/07**

Update count: **0**

Registration date

2020-10-28, 1399/08/07

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

2020-08-16, 1399/05/26

Expected recruitment end date

2021-03-19, 1399/12/29

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 treatment of necrotic mandibular molars with periapical lesion; A randomized clinical trial

Public title
Low level laser therapy and post endodontic pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients in need for root canal treatment on mandibular molars Mandibular molars with pulp necrosis diagnosed with vitality tests Mandibular molars with periapical lesions scoring 2 or 3 in accordance with the periapical index classification introduced by Ørstavik et al No pain with pulpal origin Pain on percussion with VAS > 56 Patients in good health and systemic condition determined by health history and verbal questioning
Exclusion criteria:
Periodontal probing depth greater than 3 mm Swelling or presence of sinus tract Patients taking analgesia 12 hours prior to intervention Teeth with open apices (immature or inflammatory root resorption) Teeth diagnosed to be non-restorable after the endodontic treatment in primary evaluations

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **36**

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.

Blinding (investigator's opinion)
Triple blinded

Blinding description

Patient is not aware of the research treatment group allocation and process. Care provider (endodontist) and investigator (dental student) are aware of the research treatment group allocation and process. Outcome assessor, data analyser and data safety and monitoring board are not aware of the research treatment group allocation and 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

2020-09-27, 1399/07/06

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.180

Health conditions studied

1

Description of health condition studied

Post treatment pain

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp, Pulpal gangrene

Primary outcomes

1

Description

post endodontic treatment pain

Timepoint

4, 8, 12, 24, 48, 72 hours and day 7 after endodontic treatment and laser therapy

Method of measurement

VAS ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 980 nm low level laser

Category

Prevention

2

Description

Control group: plasbo laser

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

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

Full name of responsible person

Dr Mahta Fazlyab

Street address

No.9, Neyestan 9 Ave, Pasdaran Ave

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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

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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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Mahta Fazlyab

Position

Assistant Professor, 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

Name of organization / entity

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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

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr Mahta Fazlyab
Position
Assistant Professor of Endodontics department,
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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 treatment 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