Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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No.9, Neyetan 9 Ave, Pasdaran Ave
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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
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Person responsible for updating data

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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