Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 2256 4571

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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: 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, T

Full name of responsible person
Dr Mahta Fazlyab

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr Arash Azizi

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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
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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