Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim

The aim of this study is to determine the effect of using 980 nm low power laser on pain after initial one-session endodontic treatment in mandibular molar teeth with irreversible pulpitis in patients referred to the Department of endodontics, Faculty of dentistry, Tehran medical sciences, Islamic Azad University, Tehran in 1399-1400.

Design

This will be a randomized double blind clinical trial.

Settings and conduct

This will be a randomized double 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

Inclusion criteria for patients, adults without medical history and with irreversible pulpitis with no Radiographic evidence of periapical radiolucency , patients with dental and periodontal health,teeth with irreversible pulpitis pain VAS> 56 and a percussion pain VAS< 56 According to the results of Ramalho et al criteria for inclusion in this study, performing primary endodontic treatment on mandibular molars with irreversible pulpitis for patients over 18 years of age and also long-term pulp response to cold test with Endo- Frost. Pregnant and lactating women and teeth with exposed pulp and necrosis and periapical lesions are exclusion criteria . Illiterate patients, patients with systemic disease, teeth with open apex, extracorporeal restoration, tooth loosening above grade 1, pocket depth over than 4 mm, non-maintenance teeth, with previous endodontic treatment Patients who took painkillers 12 hours before the intervention, patients who took antibiotics in the past month, and patients with acute pain were excluded from the study at the time of the intervention.

Intervention groups

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

Main outcome variables

Prevention of post endodontic treatment pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110212005804N8**
Registration date: **2020-11-12, 1399/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-12, 1399/08/22**
Update count: **0**

Registration date

2020-11-12, 1399/08/22

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2021-08-11, 1400/05/20

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 mandibular molars with irreversible pulpitis; 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 presence of irreversible pulpitis confirmed with pulp vitality tests no radiographic evidence of periapical radiolucency pulpal pain on VAS more than 56 percussion pain on VAS less than 56 Patients in good health and systemic condition determined by health history and verbal questioning
Exclusion criteria:
Pregnant and lactating women Teeth with exposed pulp and necrosis and with periapical lesion Illiterate patients Patients with systemic disease Teeth with open apex extracorporeal restoration Tooth loosing above grade 1 pocket depth over than 3 mm Unmaintainable teeth previous endodontic treatment, patients who took pain killers 12 hours before the intervention patients who took antibiotics in the past month patients with acute pain in time of intervention
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.1399.179

Health conditions studied

1

Description of health condition studied
post endodontic treatment pain
ICD-10 code
K04.0
ICD-10 code description
Pulpitis: acute irreversible

Primary outcomes

1

Description
post endodontic treatment pain
Timepoint
Before treatment, immediately after treatment, 4, 8, 12, 24, 48, 72 and the seventh day after treatment
Method of measurement
VAS ruler

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 980nm low level laser
Category
Prevention

2

Description
Control group: plasebo 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
No funding has been provided for this study and all costs will be covered by the researchers.
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
Persons

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