

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 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

mfazlyab@dentiau.ac.ir

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 loosening 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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No.9, Neyetan 9 Ave, Pasdaran Ave

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1946853314

Phone

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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

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

Specialist

Other areas of specialty/work

Dentistry

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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