# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 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

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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**
Specialist
**Other areas of specialty/work**
Dentistry
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## Person responsible for scientific inquiries

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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