Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

Evaluation the effect of low-power ۹۸۰ nm laser on intra pulpal injection pain in mandibular first and second molars with symptomatic irreversible pulpitis: A randomized, double-blind clinical trial study

Protocol summary

Study aim
Determine the effect of 980 nm low-power laser on intra pulpal injection pain in mandibular first and second molars with symptomatic irreversible pulpitis

Design
The clinical trial has a placebo group, double-blind, randomized, each group 28 people. Randomization will be done using random blocks of 4, with the help of Excel software.

Settings and conduct
A study will be conducted on patients with symptomatic irreversible pulpitis (SIP) in patients referred to the Endodontics Department, Faculty of Dentistry, Tehran University of Medical Sciences. Patients who have failed initial anesthesia and require intra pulpal injection will be randomly divided into two groups (n=28). Patients and the assessor of the study results will be blinded (double-blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18-65 years old. Patients requiring root canal therapy have signs and symptoms of irreversible pulpitis in the mandibular first and second molars in whom mandibular nerve block anesthesia has not been successful and who have pain during access cavity preparation and require intra pulpal injection. Exclusion criteria: Teeth with crown/root fractures, acute or chronic apical abscess, necrosis, damaged periodontium, or open apex. Patients who have had a history of taking long-term medications that affect pain threshold, such as painkillers, steroids, or antibiotics, in the past 24 hours.

Intervention groups
Control group: Laser sham (placebo) + intrapalpal injection: In this group, the laser will be used in the off mode. Intervention group: Low-power laser irradiation with a wavelength of 980 nm (300 J/cm2) for 30 seconds, then intrapalpal injection will be performed immediately after laser irradiation.

Main outcome variables
Pain before and during intra pulpal injection.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250831067058N1**
Registration date: **2026-04-18, 1405/01/29**
Registration timing: **prospective**

Last update: **2026-04-18, 1405/01/29**
Update count: **0**

Registration date
2026-04-18, 1405/01/29

Registrant information

Name
Ziba Ghorvei nossrat

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-31, 1405/03/10

Expected recruitment end date
2026-10-22, 1405/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation the effect of low-power ۹۸۰ nm laser on intra pulpal injection pain in mandibular first and second molars with symptomatic irreversible pulpitis: A randomized, double-blind clinical trial study

Public title
Evaluation the effect of low-power 980 nm laser on intrapulpal injection pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients requiring root canal therapy have signs and symptoms of irreversible pulpitis in the mandibular first and second molars in whom a mandibular nerve block anesthetic injection has not been successful and who have pain during access cavity preparation. Requires intra pulpal injection Has systemic health Signing a written and informed consent form Cold testing using EndoFrost will be performed on the mandibular first and second molars and the contralateral tooth. Teeth that respond positively will be included in the study. Teeth with moderate, sharp, and spontaneous pain, a preoperative VAS score greater than 5, or pain stimulated by heat or cold that persisted after removal of the stimulus, without pain on biting or tapping, and without periapical changes or lesions (periapical index ≤2) will be included in the study.
Exclusion criteria:
Teeth with crown/root fractures, acute or chronic apical abscess, necrosis, damaged periodontium, or open apex Presence of physical disability, mental problems, or facial paresthesia (tingling or numbness) History of sensitivity to local anesthetic solutions Patients who have had a history of taking long-term medications that affect pain threshold, such as painkillers, steroids, or antibiotics, in the past 24 hours Teeth that are observed as non-vital during access cavity preparation
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed using random blocks of 4, using Excel software. The randomization process will be performed by the study epidemiology consultant. To perform this process, the type of intervention assigned will be written in numerical order in sealed envelopes and, in the order of patient referral, the envelopes are opened at the time of treatment and the type of intervention is determined.
Blinding (investigator's opinion)
Double blinded
Blinding description
The study will be double-blind, so that neither the patient nor the person performing the pain assessment will be aware of the technique being used.
Placebo
Used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of School of Dentistry-Tehran University of Medical Sciences
Street address
Northern worker
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Tehran
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Postal code
1439955934
Approval date
2025-05-11, 1404/02/21
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1404.028

Health conditions studied

1

Description of health condition studied
Irreversible pulpitis
ICD-10 code
K04.0 Pulp
ICD-10 code description
Irreversible pulpitis

Primary outcomes

1

Description
Pain
Timepoint
Before and during intra pulpal injection
Method of measurement

Based on the visual analog scale (VAS): Patients will indicate their pain level on a 10-centimeter line (VAS).

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Laser sham (placebo) + intrapulpal injection: In this group, the laser will be used in the off mode.
Category
Treatment - Drugs

2

Description
Intervention group: Low-power laser irradiation with a wavelength of 980 nm (300 J/cm2) with a power of 100 milliwatts and a 400 micrometer fiber, for 30 seconds, then intrapulpal injection will be performed immediately after laser irradiation.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Dental School
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Tehran University of Medical Science
Proportion provided by this source
1
Public or private sector
Public
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
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Full name of responsible person
Dr. Mohammad Hosein Nekoofar
Position
Professor of Endodontics
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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