Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jul 2026

Effect of root canal disinfection by 980nm Diode laser on post operative pain after single visit root canal treatment of first and second mandibular molars: A randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of root canal disinfection by 980 Nanometre (nm) diode laser on post-operative pain after single visit root canal endodontic treatment of the mandibular molar with pulp necrosis

Design
The clinical trial will be performed with case and control groups with parallel groups, one-way blind, randomized by balanced block and 27 patients (totally 54 patients) in each group.

Settings and conduct
The study is committed in the endodontics department of the Faculty of dentistry, Azad University of Tehran. After Anesthesia, Isolation is accomplished with rubber dam. After access cavity preparation and determination of working length, the rotary motor will be used for filling the canals. Irrigation by sodium hypochlorite 5.25 percent will be done. Apical enlargement to size F3 will be done. Then canals will be dried by paper points. Then the patients will be placed in laser and control groups. Obturation will be performed by lateral condensation technique. The patient's pain will be recorded by Visual Analogue Scale immediately after the treatment, 4, 12, 24, 48, 72 hours and then 7 days after the treatment.

Participants/Inclusion and exclusion criteria
patients must have pulp necrosis of mandibular molar and must be between 18 to 50 year old. Non-entry criteria included teeth that have already undergone endodontic treatment, patients taking analgesia 12 hours before the intervention or have taken antibiotics in previous month, and patients who have acute pain at the time of intervention.

Intervention groups
Laser: After preparation of the canal, the laser radiation will be performed by a 980nm diode laser in the root canal. Control: Similar to the laser group, tips will be inserted into the canal but won't be activated and the steps will be simulated.

Main outcome variables
Post operative pain after Endodontic treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220529055019N1**
Registration date: **2022-09-03, 1401/06/12**
Registration timing: **prospective**

Last update: **2022-09-03, 1401/06/12**
Update count: **0**

Registration date
2022-09-03, 1401/06/12

Registrant information

Name
Mahdieh Esmaeili

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
2022-09-17, 1401/06/26

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of root canal disinfection by 980nm Diode laser on post operative pain after single visit root canal treatment of first and second mandibular molars: A randomized clinical trial

Public title
Effect of root canal disinfection by 980nm Diode laser on post operative pain after single visit root canal treatment of first and second mandibular molars
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All the patients must have pulp necrosis of mandibular molar. Patients must be between 18 to 50 years old.
Exclusion criteria:
Patients who have taken antibiotics in the month before the intervention. Patients taking analgesia 12 hours before the intervention. Teeth that have already undergone endodontic treatment. Patients who have acute pain at the time of intervention.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method is balanced block. The randomization unit of each molar tooth belongs to each single patient and only one molar tooth from each patient is included in the study. The randomization tool uses a table of printed random numbers, the odd digit of group A and the even digit of group B until the intervention in the block is filled, and then the results are recorded in the order of registration and allocation of each sample inside the sealed envelope, which at the time of the intervention The envelope will be opened. The way to make a random sequence is based on the sequence of people's referrals. The person who determines the type of random allocation of samples is the consultant of methodology and statistics of the study, who leaves the sealed envelopes at the disposal of the clinical researcher and has no role in the clinical research process. The envelopes remain sealed until the intervention and are opened in the order mentioned on the back of the envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
The steps of both groups are the same. In both the laser and placebo groups, the tips will be inserted into the canal to the working length , but in the placebo group the lasers will not be activated and only the disinfection steps by laser will be simulated. Before the operation, the two groups will be explained to the patients and all the patients will be told that you are not aware of the treatment group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Faculty of Dentistry Tehran Azad university of medical sciences,
Street address
No. 9, 9th Neyestan, Pasdaran Avenue
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Tehran
Province
Tehran
Postal code
1946853314
Approval date
2022-02-21, 1400/12/02
Ethics committee reference number
IR.IAU.DENTAL.REC.1400.170

Health conditions studied

1

Description of health condition studied
Pulp necrosis
ICD-10 code
K04.1
ICD-10 code description
Necrosis of pulp

Primary outcomes

1

Description
Pain after endodontic treatment
Timepoint
Immediately after treatment, 4 hours, 12 hours, 24 hours, 48 hours, 72 hours and 7 days after treatment
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Laser : After preparation of the canal, the laser radiation will be performed by a 980 nm diode laser in the root canal. Irradiation will be performed in 4 pulses, each pulse is laser radiation for 5 seconds and then stops for 10 seconds. The movement speed of the tip is 2 mm/s and the location of the tip is 1 mm above the apex. It will be performed with a power of 1.2 watts, and the tips with a diameter of 200 microns and a length of 15 mm go into the canal until the working length, and the laser is irradiated by rotation and then exits the channel.

Category
Treatment - Devices

2

Description
Control group: Similar to the laser group, tips will be inserted into the canal but won't be activated and the steps will be simulated.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Endodontics department of Faculty of Dentistry, Islamic Azad University of medical sciences

Full name of responsible person
Ehsan Esnaashari

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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?
Yes

Title of funding source
Islamic Azad University

Proportion provided by this source
100

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
Islamic Azad University

Full name of responsible person
Mahdieh Esmaeili

Position
Student

Latest degree
A Level or less

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
Yes - There is 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
Yes - There is 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
Not applicable

Title and more details about the data/document
All potential data can be shared after the participants are unidentifiable.

When the data will become available and for how long
Access period starts from 2024

To whom data/document is available
Only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used
The data can be used for scientific researches.

From where data/document is obtainable
Mahdieh Esmaeili mahdiehesmaeili1998@gmail.com

What processes are involved for a request to access data/document
After submitting the request, the request will be reviewed and answered as soon as possible.

Comments