

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of 810nm diode laser on the onset and depth of anesthesia during root canal treatment of mandibular first molars with symptomatic irreversible pulpitis.

Protocol summary

Study aim

effect of diode laser 810nm before anesthesia on onset and depth of anesthesia during treatment of mandibular first molar with irreversible pulpitis

Design

parallel group, double blind, randomised controlled trial

Settings and conduct

44 patients with symptomatic irreversible pulpitis were included. Randomly allocated into laser and placebo group. In treatment group low level laser therapy is applied on periapical region of first mandibular molar area, all teeth anesthetized using 1.8 ml of 2% lidocaine delivered with inferior alveolar nerve block technique. Root canal therapy is initiated after 15 minutes, the patients were asked about felt pain during this procedure using HP-VAS, the person who performs root canal therapy is unaware of aims of study and trial protocol. If the patient felt moderate to severe pain that cannot be tolerated, the procedure is halted and receives supplementary anesthesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of irreversible pulpitis, understanding HP-VAS, the existence of contralateral canine without history of previous restoration or trauma, the patient should be in a position to obtain information, about written informed consent, minimum age of 18 and maximum age of 60 years. Exclusion criteria: history of systemic conditions, use of cardiac pacemaker, signs of periapical lesion in the radiographic examination, history of use of antibiotics over the past week or analgesics over the last 24 hours.

Intervention groups

Intervention group: Radiation of a diode laser with a power of 300 mW and a density of 15 J/cm² in the buccal region of first mandibular molar for 20 seconds. Control group: Placebo laser radiation (energy free) in the buccal region of first mandibular molar for 20 seconds.

Main outcome variables

pulpal anesthesia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181222042076N1**

Registration date: **2019-10-06, 1398/07/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-06, 1398/07/14**

Update count: **0**

Registration date

2019-10-06, 1398/07/14

Registrant information

Name

leila ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3778 1139

Email address

leilaghasemi681@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-03, 1397/11/14

Expected recruitment end date

2020-02-03, 1398/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of 810nm diode laser on the onset and depth of anesthesia during root canal treatment of mandibular first molars with symptomatic irreversible pulpitis.

Public title
The effect of 810nm diode laser on mandibular first molar anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 diagnosis of irreversible pulpitis via thermal tests
 understanding HP-VAS the existence of contralateral canine without history of previous restoration or trauma
 the patient should be in access to obtain information about written informed consent minimum age of 18 and maximum age of 60 years
Exclusion criteria:
 history of systemic conditions, such as cardiovascular diseases, diabetes mellitus, cancer or psychiatric diseases use of cardiac pace maker signs of periapical lesion in the radiographic examination of the examined tooth history of use of antibiotics over the past week or analgesics over the last 24 hours

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
six digit number created with random number generator (excel 2017) the allocation process is concealed by placing treatment group paper in opaque sealed envelope.

Blinding (investigator's opinion)
Double blinded

Blinding description
participants, principle investigators includes: the person that do laser application, the person that perform local anesthesia, the person that perform root canal therapy procedure and the person that collect the results.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan university of medical science

Street address

Hamadan university of medical science, Fahmieh S.t, Pazhouhesh Sq, Beasat Blv,

City

Hamadan

Province

Hamadan

Postal code

65417838741

Approval date

2019-01-22, 1397/11/02

Ethics committee reference number

IR.UMSHA.REC.1397.695

Health conditions studied

1

Description of health condition studied

IOCAL anesthesia

ICD-10 code

Y48.3

ICD-10 code description

IOCAL ANAESTHETICS

Primary outcomes

1

Description

pulpal anesthesia

Timepoint

During pulpectomy

Method of measurement

HP-VAS Pain assessment tool

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Radiation of a diode laser with a power of 300 mW and a density of 15 J/cm² In the buccal region of first mandibular molar for 20 seconds

Category

Treatment - Devices

2

Description

Control group: Placebo laser radiation (energy free) in the buccal region of first mandibular molar for 20 seconds

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Endodontic department, School of dentistry, Hamadan university of medical science

Full name of responsible person

Rooholah Behrouzi

Street address

Shahid Fahmideh

City

Hamadan

Province

Hamadan

Postal code

65417838741

Phone

+98 81 3838 1059

Email

roohbeh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr.Saeed Bashirian

Street address

Shahid Fahmideh

City

Hamadan

Province

Hamadan

Postal code

65417838741

Phone

+98 81 3838 1059

Fax

+98 81 3838 1085

Email

roohbeh@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

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

Hamedan University of Medical Sciences

Full name of responsible person

Rooholah Behroozi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Department of endodontics, School of dentistry, Hamadan university of medical sciences, Shahid Fahmide st., Pazhuhesh sq.

City

Hamadan

Province

Hamadan

Postal code

65417838741

Phone

+98 81 3838 1059

Fax

+98 81 3838 1085

Email

roohbeh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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Position

Assistant professor

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Fax
+98 81 3838 1085
Email
roohbeh@gmail.com

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roohbeh@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

we will provide information regarding primary outcome measure, sex and age range of precipitants, response to treatment

When the data will become available and for how long

after publication of the final article

To whom data/document is available

researchers who works in university

Under which criteria data/document could be used

the data will provide for using in review studies or future clinical trials if cited as regular

From where data/document is obtainable

leilaghasemi681@yahoo.com 09132157580 leila ghasemi

What processes are involved for a request to access data/document

requesting via email that takes maximum one month after receiving the request

Comments

Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Rooholah Behroozi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Department of endodontics, School of dentistry,
Hamadan university of medical sciences, Shahid
Fahmide st.,Pazhuhesh sq.
City
Hamadan
Province
Hamadan
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Phone
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Fax
+98 81 3838 1085