Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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 diod laser 810nm before anesthesia on onset and deep of anesthesia during treatment of mandibular first molar with irriversible pulpitis

Design
parallel group, double blind, randomised controlled trial

Settings and conduct
44 patient with symptomatic irreversible pulpitis were included. Randomly allocated in to 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 perform root canal therapy is unaware of aims of study and trial protocol. if the patient felt moderate to severe pain that cannot be tollerated, the procedure is halted and receive supplementary anesthesia.

Participants/Inclusion and exclusion criteria
Inclusion criteria diagnosis of irreversible pulpitis understanding HP-VAS the existence of contralateral canine without histrory 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 use of cardiac pace maker 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

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Iran (Islamic Republic of)

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+98 31 3778 1139

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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 histrory 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,

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Province

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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

lOCAL anesthesia

ICD-10 code

Y48.3

ICD-10 code description

lOCAL 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
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Sponsors / Funding sources

1

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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
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
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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