

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A comparison of two dentin desensitizer protocols with diode laser(810 nm) in terms of intrapulpal temperature in patients with irreversible pulpitis

Protocol summary

2018-05-04, 1397/02/14

Study aim

pulpal temperature evaluation after desensitization protocol by diode laser

Design

Parallel group, randomised controlled trial with 45 samples. Randomisation sequence will be carried out by table of random number(www.randomizer.org).

Settings and conduct

Laser Department of Tehran azad university of Dentistry

Participants/Inclusion and exclusion criteria

inferior or superior incisors or premolars with irreversible pulpitis with intact buccal surface.

Intervention groups

In group 1, diode Laser (810 nm) irradiation will be done with 200 microne tip size and power of 1 W for 10s, continuous and non-contact mode(1 mm from labial or buccal surface of teeth) and in group 2 irradiation will be done by 0.5 W, non-contact and continuous mode(2mm from tooth surface). Temperature changes will be recorded in these group. In control group, after access cavity preparation, temperature changes will be recorded.

Main outcome variables

temperature rising during laser emitting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170923036331N3**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

Registrant information

Name

Zohreh Khalilak

Name of organization / entity

Islamic Azad University- Dental school- Endodontic department

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

none

Expected recruitment start date

2018-04-08, 1397/01/19

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

2017-12-06, 1396/09/15

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

A comparison of two dentin desensitizer protocols with diode laser(810 nm) in terms of intrapulpal temperature in patients with irreversible pulpitis

Public title

The effect of diode laser on pulpal temperature

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Vital teeth with irreversible pulpitis. Buccal surface should be intact. Teeth should be fully erupted and mature. Patients' age is between 25 to 50

Exclusion criteria:

patients with systemic problems, any kind of drug usage including analgesics and sedative drugs and smokers necrotic, traumatized, immature or calcified teeth

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **45**

Actual sample size reached: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization is individual stratified randomization. Strata is including incisors and premolars. Randomization have done by random number generator (<https://www.random.org>) were used for randomization.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Islamic azad university of Tehran, Dental branch

Street address

Pasdaran, Neyestan 9

City

Tehran

Province

Tehran

Postal code

19585175

Approval date

2017-03-12, 1395/12/22

Ethics committee reference number

IR.IAU.DENTAL.REC.1395.37

Health conditions studied

1

Description of health condition studied

intrapulpal temprature rise

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Intrapulpal temprature

Timepoint

2, 4, 6, 8, 10 seconds during Laser irradiation in group 1 and at 2, 4, 6, 8, 10, 15, 30, 45, 60 seconds during Laser irradiation in group 2 and temprature will be evaluate in control group up to 10 minutes.

Method of measurement

thermometer

Secondary outcomes

empty

Intervention groups

1

Description

interventional group 1: Laser irradiation will be done with following parameters: 1 W for 10 seconds, non-contact with continious mode by 200 micron tip at cervical portion of teeth (1mm from tooth surface). Thermocoupl will be placed through access cavity and will be fixed by cavite.

Category

Treatment - Other

2

Description

Intervention group 2: Laser irradiation will be done with following parameters: 0.5 W for 60 seconds, non-contact with continious mode and 60 j/cm2 energy density(2mm from tooth surface). Thermocoupl will be placed through access cavity and will be fixed by cavite.

Category

Treatment - Other

3

Description

Control group: access cavity preparation and temprature evaluation without laser irradiation

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic azad university of Tehran, Dental branch

Full name of responsible person

Delaram Bineshmarvasti

Street address

No4, Neyestan 9, Pasdaran ave, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research institution of Islamic azad university of
Tehran, Dental branch

Full name of responsible person

Arash Azizi

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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

Research institution of Islamic azad university of Tehran,
Dental branch

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**

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic azad university of Tehran, Dental branch

Full name of responsible person

Delaram binesh marvasti

Position

Post graduate student of endodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic azad university of Tehran Dental branch

Full name of responsible person

Zohreh khalilak

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran Islamic azad university of dentistry

Full name of responsible person

Delaram bineshmarvasti

Position

post-graduate student of endodontics

Latest degree

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Other areas of specialty/work

Dentistry

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Web page address**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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

no condition

From where data/document is obtainable

Dr. Delaram Bineshmarvasti 09122347608

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

phone contact/give their email address /it takes one week to send data to the email address

Comments