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

Study aim
pulpal temperature evaluation after desensitization protocol by diode laser

Design
Parallel group, randomised controlled trial with 45 samples. Randomisation sequance 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, continious 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 continious 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
2018-05-04, 1397/02/14

Registrant information

Name
Zohreh Khalilak

Name of organization / entity
Islamic Azad University- Dental school- Endodontic department

Country
Iran (Islamic Republic of)

Phone
+98 22564571

Email address
z_khalilak@dentaliau.ac.ir

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 errupted 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, troumatized, 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 temperature 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 temperature 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

City
Tehran

Province
Tehran

Postal code
19585175

Phone
+98 21 2256 4570

Email
dlrmbm@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Resaerch institution of Islamic azad university of Tehran، Dental branch

Full name of responsible person
Arash Azizi

Street address
No.4, Neyestan 9, Pasdaran

City
Tehran

Province
Tehran

Postal code
19585175

Phone
+98 21 2256 4570

Email
dlrmbm@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Resaerch 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

Street address
Pasdaran, 9th Neyestan

City
Tehran

Province
Tehran

Postal code
19585175

Phone
+98 21 2278 3793

Fax

Email
dlrmbm@yahoo.com

Web page address

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
Dentistry

Street address
Pasdaran, Neyestan 9

City
Tehran

Province
Tehran

Postal code
19585175

Phone
+98 21 2256 4571

Fax

Email
z_khalilak@dentaliau.ac.ir

Web page address

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
Medical doctor
Other areas of specialty/work
Dentistry
Street address
No. 4, Neyestan 10, Pasdaran ave.,Tehran
City
Tehran
Province
Tehran
Postal code
19585175
Phone
+98 21 2256 4570
Fax
Email
dlrmbm@yahoo.com
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