

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of the use of the two types of Nd: YAG 1064 nm laser) (Er: YAG (2940 nm) on thermal changes of the premolars human pulp during removal of ceramic brackets (clinical trial)

Protocol summary

Study aim

Determine the mean pulp temperature before and after laser irradiation in the studied groups

Design

The clinical trial included two arm parallel groups, consisting of 24 samples, randomized, double-blind, and randomized by www.random.org

Settings and conduct

The study was conducted as a clinical trial with random sampling at the Faculty of Dentistry of Islamic Azad University. The study is double blinded and the evaluator and investigator are blind.

Participants/Inclusion and exclusion criteria

All the patients were in good health as determined by health history and verbal questions. All the participants are not allowed to take any kind of medications. Teeth included should not have any kind of restorations, caries, hypocalcification and cracks. Teeth should have normal reaction to cold test. Teeth should not be loose or have swelling in the soft tissue around. The radiographic findings of these teeth should be free from damage in PDL and the area around the root. If any of the above items does not exist, patients will not be allowed to go to study.

Intervention groups

In the first group, an Er: YAG laser will be used at 2940 nm wavelength lightweaker (LightWalker AT, Fotona, Ljubljana, Slovenia). In the second group, an Nd: YAG laser with a wavelength of 1064 nm will be used the LightWalker (LightWalker AT, Fotona, Ljubljana, Slovenia)

Main outcome variables

temperature changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110212005804N4**

Registration date: **2019-10-15, 1398/07/23**

Registration timing: **retrospective**

Last update: **2019-10-15, 1398/07/23**

Update count: **0**

Registration date

2019-10-15, 1398/07/23

Registrant information

Name

Mahta Fazlyab

Name of organization / entity

Islamic Azad University, Dental Branch, Tehran

Country

Iran (Islamic Republic of)

Phone

+98 21 2256 4571

Email address

mfazlyab@dentiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-01, 1397/11/12

Expected recruitment end date

2019-09-21, 1398/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of the use of the two types of

Nd: YAG 1064 nm laser) (Er: YAG (2940 nm) on thermal changes of the premolars human pulp during removal of ceramic brackets (clinical trial)

Public title

effect of laser on the pulp changes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All the patients were in good health as determined by health history and verbal questioning. All the participants are not allowed to take any kind of medications. Teeth included in this study should not have any kind of restoration ,caries , hypocalcification or cracks. Teeth should have normal reaction to cold test and this reaction will compare to the same tooth in the other quadrant. Teeth should not be loose or have swelling in the soft tissue around and be sensitive to the percussion and palpation. the radiographic findings of these teeth should be free from damage in PDL and the area around the root.

Exclusion criteria:

Patients with systemic problems modifying the treatment process and taking all kinds of systemic drugs will not be included in the study. The teeth with cracks ,restorations ,caries and hypocalcification will not be included in the study. If the tooth in the radiographic clinical examination shows the sign of any radicular lesion, it will be excluded. The patient's sensitivity to cold, heat, or chewing pressure on the teeth that causes the teeth to fail to enter the study.

Age

From **12 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **6**

More than 1 sample in each individual

Number of samples in each individual: **4**

The samples consisted of four first or second premolar teeth in one jaw between 12 and 30 years old who needed to remove these teeth for orthodontic treatment plan.

Randomization (investigator's opinion)

Randomized

Randomization description

Samples are placed in a randomized 4-block by the method of Balanced Block. The randomization process is performed by an individual other than the investigator, and information about the sample intervention is stored in sealed envelopes in order to randomize the excel software.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is aware of the research process. The analyzer is not aware of the investigation process. The evaluator is not aware of the research process.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee, Faculty of Dentistry, Islamic Azad University

Street address

No. 9, Faculty of Dentistry Islamic Azad University, 9th neyestan Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Approval date

2018-12-31, 1397/10/10

Ethics committee reference number

IR.IAU.DENTAL.REC.1397.029

Health conditions studied**1****Description of health condition studied**

pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes**1****Description**

temperature changes

Timepoint

The temperature immediately after laser irradiation and removal of the bracket (TL) will be measured and recorded by the thermometer (Hanyoungnux, series, D55, Korea). The temperature will then be recorded in the intervals of one minute for 10 minutes (TL1 to TL10).

Method of measurement

Immediately after the cavity is prepared, the temperature of the pulp will be measured (Taccess).

Then, the temperature changes will be recorded as T1 to T10 for up to 10 minutes at 1 minute intervals. The temperature test was continued up to 2 minutes after the temperature was stabilized to ensure temperature stability and then the data were evaluated before the onset of the main treatment and recorded as the initial temperature before the radiation (TBase). After laser irradiation and debonding the brackets, the temperature will be measured immediately (T laser), and then the temperature will be recorded as TL1 to TL10 for up to 1 minute intervals.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: In the first group,. An Er: YAG laser will be used at 2940 nm wavelength lightweaker (LightWalker AT, Fotona, Ljubljana, Slovenia). The handpiece will be used for contact type (H14 C, Fotona, Slovenia). The fiber used is Cylinderry and its tip, with a length of 8 mm and a diameter of 3.1 mm. The settings for this mounting bracket are as follows: 1.2 W, 600 MJ, 2 Hz, Pulse Long without spray of weather

Category

Treatment - Devices

2

Description

Second inversion group:In the second group, a Nd: YAG laser with a wavelength of 1064 nm will use the LightWalker AT, Fotona, Ljubljana, Slovenia, which has the characteristics as follows: 0.2 millisecond pulses and 3 watts for 3 seconds The outer diameter of the fiber is 400 microns and its tip is 1 mm from the surface of the bracket and perpendicular to the bracket surface. After the prescribed period of radiation, the bracket device is removed with the plug-in.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of dentistry of Islamic Azad university

Full name of responsible person

Dr Mahta Fazlyab

Street address

No. 9, Faculty of dentistry of Islamic Azad university, 9th Neyestan Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Fax

+98 21 2256 4577

Email

dr.mfazlyab@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Arash Azizi (Vice chancellor of research, Islamic Azad University of medical sciences)

Street address

No. 9, 9th Neyestan Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

dr.mfazlyab@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor of research, Islamic Azad University of medical sciences

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

Full name of responsible person

Dr Mahta Fazlyab

Position

Assistant Professor of Endodontics department, Faculty of Dentistry of Islamic Azad University

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 9, 9th Neyestan Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

dr.mfazlyab@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr Mahta Fazlyab

PositionAssistant Professor of Endodontics
Department, Faculty of Dentistry of Islamic Azad University**Latest degree**

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 9, 9th Neyestan Ave, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

dr.mfazlyab@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Mahta Fazlyab

Position

Assistant Professor of Endodontics

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

number 4, 10th Neyestan, Pasdaran st

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2275 2019

Fax

+98 21 2205 5386

Email

dr.mfazlyab@gmail.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

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

Only part of the data, such as the key outcome information or the like, can share.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Readers of the published article

Under which criteria data/document could be used

In case of publish the article

From where data/document is obtainable

Target journal

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

Refer to the desired journal site

Comments