

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

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

#### Protocol summary

##### Study aim

Comparing the Nd: YAG and Er: YAG lasers for ceramic brackets debonding on histological changes of pulp in human premolars

##### Design

Randomized single-blind clinical trial on two study groups consisting of 36 samples that allocate into random blocks using balanced block technique

##### Settings and conduct

The study is carried out in the Faculty of Dentistry of Islamic Azad University. The brackets are debonded from the teeth by laser and immediately extracted. And teeth are fixed in 10% formalin solution. The specimens are prepared according to the ISO7405 standard and prepared by a pathologist examiner after providing along the longitudinal axis and staining. According to this standard, grade 0, refers to samples without inflammation, grade 1; to mild inflammation, grade 2; to moderate inflammation, grade 3; to severe inflammation and grade 4 to abscess formation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with two premolar teeth in one jaw that need extraction for orthodontic treatment.  
Exclusion criteria: Patients with systemic conditions modifying the treatment and taking any systemic medicine, teeth with cracks, restorations, caries and hypocalcification, any sign of radicular lesion in radiographic examination, or tooth sensitivity to cold, heat or bite pressure.

##### Intervention groups

First intervention group: Er: YAG laser with 2940 nm wavelength (Fotona, Slovenia) will be used for bracket debonding. The irradiation will last for 3 seconds and the beam is parallel to tooth surface and in the tooth-bracket interface. In the second group : Nd: YAG laser with 1064 nm wavelength (Fotona, Slovenia) will be used for bracket debonding. The irradiation will last for 3 seconds

and the beam is parallel to tooth surface and in the tooth-bracket interface.

##### Main outcome variables

histologic changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20110212005804N6**

Registration date: **2019-12-21, 1398/09/30**

Registration timing: **retrospective**

Last update: **2019-12-21, 1398/09/30**

Update count: **0**

##### Registration date

2019-12-21, 1398/09/30

##### 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**

2019-04-10, 1398/01/21

**Actual recruitment end date**

2019-11-19, 1398/08/28

**Trial completion date**

2019-11-19, 1398/08/28

**Scientific title**

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

**Public title**

effect of laser on pulp histology

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with at least two premolar teeth in a single jaw that need to be extracted for orthodontic treatment.

**Exclusion criteria:**

Patients with systemic problems that modify the treatment procedure Patients taking any systemic medicine Teeth with cracks, existing restorations, caries and hypocalcification. Any radicular lesion in clinical or radiographic examination The tooth sensitivity to cold, heat, or bite pressure on the teeth

**Age**

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

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

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

**Sample size**

Target sample size: **28**

More than 1 sample in each individual

Number of samples in each individual: **2**

Samples include one premolar tooth on the left and one premolar on the right side of one jaw. A total of 28 patients will be included providing 28 pairs of teeth (totally 56 samples) for each intervention group.

Actual sample size reached: **28**

More than 1 sample in each individual

Actual sample size in each individual: **2**

Samples included one premolar tooth on the left and one premolar on the right side of one jaw. A total of 28 patients were included providing 28 pairs of teeth (totally 56 samples) for each intervention group.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The samples will be randomly allocated to double blocks using random-block technique. Random allocation will be done using Excel software by a blinded person who is not among the investigators and the intervention details will

be kept in sealed and coded pockets. As a result patient allocation will be done based on age and gender. The pockets have 28 numbers for the first intervention groups and 28 numbers for the second intervention groups.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The evaluation process is done by someone other than the practitioner who does the operation. He does not have access to patient's information, either. Moreover, histological evaluation is done in the absence of patient and the practitioner.

**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.1397.030

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

pulpitis

**ICD-10 code**

K04.0

**ICD-10 code description**

Pulpitis

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

histologic changes

### Timepoint

Immediately after laser irradiation and bracket debonding the teeth are extracted and sent for preparation and histological evaluation.

### Method of measurement

The specimens will be evaluated according to ISO7405 standard.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

First intervention group: Er: YAG laser with 2940 nm wavelength (Fotona, Slovenia) will be used for bracket debonding. The parameters are based on device pre-sets as follows: 1.2 W, 600 MJ, 2 Hz, lung pulse without air spray. The irradiation will last for 3 seconds and the beam is parallel to tooth surface and in the tooth-bracket interface. After radiation, the bracket is removed with a plugger.

#### Category

Treatment - Devices

### 2

#### Description

Second inversion group: Nd: YAG laser with 1064 nm wavelength (Fotona, Slovenia) will be used for bracket debonding. The parameters are based on device pre-sets as follows: pulse length 0.2 millisecond and energy 3 watts for 3 seconds. The irradiation will last for 3 seconds and the beam is parallel to tooth surface and in the tooth-bracket interface. After radiation, the bracket is removed with a plugger.

#### 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

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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

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##### Email

drarashazizi@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Islamic Azad University

#### 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

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

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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**Other areas of specialty/work**  
Dentistry  
**Street address**  
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**City**

## 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

Researchers and college students who are involved in the treatment of patients in common can use data

### Under which criteria data/document could be used

All the clinicians who use laser to debond ceramic brackets can access the documents using the following address. dr.Mahta Fazlyab dr.mfazlyab@yahoo.com Faculty of dentistry of Islamic Azad university +982122564571 No. 9, Faculty of dentistry of Islamic Azad university, 9th Neyestan Ave, Pasdaran Ave

### From where data/document is obtainable

Applicants can contact the person responsible for the article to receive the information. dr.Mahta Fazlyab dr.mfazlyab@yahoo.com Faculty of dentistry of Islamic Azad university +982122564571 No. 9, Faculty of dentistry of Islamic Azad university, 9th Neyestan Ave, Pasdaran Ave

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

Demand by email to the person responsible for the article dr.Mahta Fazlyab dr.mfazlyab@yahoo.com

### Comments