Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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
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No. 9,Faculty of Dentistry Islamic Azad University,9th neyestan Ave,Pasdaran Ave
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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 invertion 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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
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Person responsible for updating data

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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
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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