Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Determining the effect of laser corticotomy on canine tooth retraction rate Dez orthodontic patients of Yazd Shahid Sadoughi Dental School who need to remove the first maxillary premolars

Protocol summary

Study aim
Evaluation of the effect of laser corticotomy on canine tooth retraction rate

Design
Clinical trial with parallel groups, one-way randomized blind, on 12 patients. Lottery method was used for randomization.

Settings and conduct
In this one-way blind study, 12 patients from the waiting list of the orthodontic department of Yazd Dental School who need to draw the first maxillary premolars for orthodontic treatment are selected using a randomization table. In these patients, the first maxillary premolars are drawn. And the aligning & leveling step is done to reach 0.017.0.025 stainless steel wire. Use chlorhexidine mouthwash for one minute, then infiltration anesthesia with injection of lidocaine with epinephrine 1: 80,000 is used for these patients. Then, using the Er: YAG laser, random corticotomy is performed on one side of the maxilla. Spring coil with force of 150 g is applied to force canine retraction.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with class I malocclusion who need bilateral traction of the first maxillary molars due to severe crowding or dental protrusion ,Patients with Class II malocclusion with maxillary dentoalveolar protrusion who require bilateral maxillary first premolars and canine retraction as part of an orthodontic treatment plan (camouflage treatment),Vital teeth with normal periodontium and no root resorption. Exclusion criteria:Poor oral hygiene Patients treated with drugs that affect the orthodontic movement of teeth.

Intervention groups
Laser corticotomy on one side of the upper jaw of orthodontic patients for whom the first premolars have been extracted

Main outcome variables
Study groups , Canine receding rate ,Anchorage loss rate, Pain score ,Pulp life test and Salcus depth

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210531051460N1**
Registration date: **2021-07-27, 1400/05/05**
Registration timing: **prospective**

Last update: **2021-07-27, 1400/05/05**
Update count: **0**

Registration date
2021-07-27, 1400/05/05

Registrant information

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Mohammad Hossein toodeh zaeim

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-06, 1400/05/15

Expected recruitment end date
2021-09-06, 1400/06/15

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the effect of laser corticotomy on canine tooth retraction rate Dez orthodontic patients of Yazd Shahid Sadoughi Dental School who need to remove the first maxillary premolars

Public title

Effect of lasercision corticotomy on the rate of canine retraction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with class l malocclusion who require bilateral maxillary first maxillary filling due to severe crowding or dental protrusion. Patients with class II malocclusion with maxillary dentoalveolar protrusion who require bilateral maxillary first premolars and canine retraction as part of an orthodontic treatment plan (camouflage treatment). Vital teeth with normal periodontium and no root resorption. The presence of both the first and second maxillary molars. Lack of systemic disease, craniofacial syndromes and deformities. No previous orthodontic treatment. Lack of facial asymmetry. Periodontal health. No history of anterior maxillary surgery. Do not take drugs that affect orthodontic movements such as corticosteroids, hormonal therapy and tricyclic antidepressants. No severe liver or kidney disease Absence of systemic conditions such as diseases that are immunocompromised or blood disorders, diabetes, etc. The natural structural shape of the canine. Acceptable oral hygiene (index plate below 30%). No vitamin D deficiency or hyperparathyroidism and osteoporosis.

Exclusion criteria:

Poor oral hygiene Patients treated with drugs that affect the orthodontic movement of teeth. Patients whose canine and second molars have necrosis.

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method is used. The randomization unit is individual and the randomization tool is the use of a random number table in such a way that all people for whom the first premolars are extracted and are in the pre-retraction stage. A number is assigned. Then, in the randomization table, we close the eyes and select the starting point, and we proceed to the same row or column, and the numbers that are smaller than the total number of people are selected to the number of the sample size, ie 13 Let's reach. Sealed bags are used to randomize which side of the laser corticotomy is to be performed.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the outcome assessor and the data analyst are blinded so that the canon retraction assessor and the data analyst are not aware of which side is performing the intervention and which is the control side. In this study, it is not possible to blind participants because our intervention is laser corticotomy.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address

Dahe Fajr Boulevard.Imam Reza Street.Shahid Sadoughi university of medical science.Yazd.Iran

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Province

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8914881167

Approval date

2021-07-12, 1400/04/21

Ethics committee reference number

IR.SSU.REC.1400.028

Health conditions studied

1

Description of health condition studied

The rate of canine tooth regression

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The rate of canine regression

Timepoint
The first month, the second month, the third month and the fourth month after laser corticotomy
Method of measurement
First, a three-dimensional scan is prepared from the study casts prepared each month. The reference lines in the scans include the midpalatal ridge and the Roga line. The Roga line is drawn from the midpoint of the third Roga on the right side of the palate perpendicular to the midline.

Secondary outcomes

1

Description
Anchorage loss
Timepoint
Pain score
Method of measurement
vitality test

Intervention groups

1

Description
Intervention group: In the area of the extracted premolar tooth, one side of the maxilla is randomly performed with laser corticotomy. During one session using the er: yag laser, corticotomy is performed in this area and the canine retraction rate is assessed within four months and compared with the control group.
Category
Treatment - Devices

2

Description
Control group: No intervention is performed in the area of the extracted premolars on the other side of the maxilla, and the amount of canine retraction in this sect is evaluated within four months and compared with the intervention group.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthodontics Department of Shahid Sadoughi university of Medical science,Yazd
Full name of responsible person
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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
Yazd University of Medical Sciences
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
Yazd University of Medical Sciences
Full name of responsible person
Negin Karimi Sardari
Position
Orthodontics resident
Latest degree
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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After identifying individuals, it is possible to share all patient variables.
When the data will become available and for how long
Access period starts 6 months after the results are published.
To whom data/document is available
Researchers working in academic and scientific institutes of prestigious scientific research journals.
Under which criteria data/document could be used
In order to use the documents of this study for other studies and researches to apply the results.
From where data/document is obtainable
Responsible person in this field Negin Karimi to the email address negin.karimi97@yahoo.com
What processes are involved for a request to access data/document
The applicant can send his/her request to the mentioned email address along with her introduction and the reason for the request, and receive the information as soon as possible (finally 7 to 10 days).
Comments