Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of low level laser therapy in relapse of rotated premolar teeth in patients under fixed orthodontics treatment

Protocol summary

Study aim

Determining amount of relapse of rotated premolar teeth under laser therapy and control group after 6 weeks Determining the relationship between premolar rotation before orthodontics treatment on relapse Comparison of average relapse of rotated premolars under laser therapy with control group Determining the relationship between time duration of correction of tooth rotation on relapse

Design

A randomized clinical trial with a parallel group design of 12 patients with 24 rotated premolar teeth. Simple randomization is performed in which individuals are divided into two groups of intervention and non-intervention based on random numbers.

Settings and conduct

In Kerman dental school, for controlling relapse, one of rotated premolars will be irradiated with a diode low-level laser with a density of 35.7 J/cm2 two times a week for 4 weeks. No intervention on the other premolar will be applied. Arch wire will be removed for 6 weeks from those teeth to let them relapse.

Participants/Inclusion and exclusion criteria

Patients under fixed orthodontics treatment with at least 2 rotated premolar teeth with a minimum rotation of 30 degrees on both sides of the upper or both sides of the lower arch were chosen. Patients shouldn't have any systemic disease. Excluded patients are those with pre-extracted or missing teeth, those who had tooth extraction for orthodontic reasons, periodontal disease and poor oral hygiene, severe caries and restorations extended to the cementoenamel junction (CEJ). Patients who take medicine which inhibits bone metabolism and pregnant patients were also excluded.

Intervention groups

One of the rotated premolars on one side of the arch will be irradiated with a diode low-level laser. No intervention (control group) will be applied to the other tooth. The arch wire will be removed from those teeth for 6 weeks.

Main outcome variables

Value of relapse in lased and control group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190511043559N1**
Registration date: **2019-09-13, 1398/06/22**
Registration timing: **retrospective**

Last update: **2019-09-13, 1398/06/22**
Update count: **0**

Registration date

2019-09-13, 1398/06/22

Registrant information

Name

Fatemeh .

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3211 9028

Email address

abdi_201339@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-06, 1397/12/15

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of low level laser therapy in relapse of rotated premolar teeth in patients under fixed orthodontics treatment

Public title
Laser effect on orthodontics relapse

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with full permanent dentition under orthodontics treatment with at least two rotated premolar teeth of 30 degrees rotation on both side of upper or both side of lower arch Dental rotation should have been corrected Patient with no pre-extracted or missing teeth Patient should not have extracted teeth for orthodontic purpose Patients of 12 years old or over

Exclusion criteria:
Pregnancy Patients with systemic diseases Patients with periodontal disease and poor oral hygiene Teeth with severe caries and restorations extended to CEJ Taking medications that interfere with bone metabolism

Age
From **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **24**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patients with full permanent dentition under orthodontic treatment with at least two rotated premolars on both side of upper or both side of lower arch

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is performed in which individuals are divided into two groups of intervention and control based on random numbers.

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
Ethics committee of Kerman University of Medical Sciences

Street address
Orthodontics Depatment, Kerman Dental School, Shafa Ave, Kerman Town

City
Kerman

Province
Kerman

Postal code
7618759689

Approval date
2019-07-30, 1398/05/08

Ethics committee reference number
IR.KMU.REC.1398.206

Health conditions studied

1

Description of health condition studied
Relapse of rotated premolar teeth in patients under fixed orthodontics treatment

ICD-10 code
Z00-Z99

ICD-10 code description
Factors influencing health status and contact with health services

Primary outcomes

1

Description
Dental relapse

Timepoint
At the end of study

Method of measurement
Digimizer software

Secondary outcomes

1

Description
Rotation of premolar tooth

Timepoint
Before orthodontics treatment

Method of measurement
Digimizer software

2

Description
Time duration after correction of tooth rotation

Timepoint
At the start of study
Method of measurement
Month numbers

Intervention groups

1

Description
Intervention group: One of the patient's rotated premolar will be irradiated with low-level Indium Aluminum Arsenide diode laser (Epic10, Biolase USA, wavelength 940 nm) 2 times a week for 4 weeks with a density of 35.7 J/cm2. Laser probe with the power of 500 milliwatt contacts the gingival tissue of one-third coronal root surface. This irradiation is applied on 2 points around the tooth including the lingual and buccal side. Irradiation continues for 120 seconds on each point. The final archwire will be removed and the alginate impression will be taken and poured with dental stone. casts will be scanned with a scanner (DentalDirekt DD Argus M2 UHD) (T1). Then archwire will be removed for 6 weeks from the rotated teeth to let the teeth relapsing. After 6 weeks the second impression will be taken and casts will be poured and scanned (T2). After that casts will be analyzed using Digimizer software for measuring dental relapse.
Category
Prevention

2

Description
Control group: Another rotated premolar of the patient falls in the control group which will not get any laser irradiation. After completion of the intervention group's laser therapy, alginate impression will be taken and final archwire will be removed for 6 months to let the teeth relapsing. After 6 months, the alginate impression is taken again and casts are prepared. afterwards casts will be analysed using Digimizer software for the magnitude of relapse.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Orthodontics Department, Kerman Dental School
Full name of responsible person
Fatemeh Abdi
Street address
Shafa Ave, Kerman Town
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Email
dentistryschool@kmu.ac.ir
Web page address
http://kmu.ac.ir/fa/sd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
Ebn Sina Ave, Kerman Town
City
Kerman
Province
Kerman
Postal code
761691713555
Phone
+98 34 3226 3815
Email
kmu_research@yahoo.com
Web page address
http://kmu.ac.ir/fa/vcrt
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Abdi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dentistry

Street address
Orthodontics Depatment, Kerman Dental School, Shafa Ave, Kerman Town
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Email
abdi_201339@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Neda Sinaee
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Orthodontics
Street address
Orthodontics Department, Kerman Dental School, Shafa Ave, Kerman Town
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Email
nedasinaee@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Abdi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
orthodontics
Street address
Orthodontics Depatment, Kerman Dental School, Shafa Ave, Kerman Town
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 9021
Email
abdi_201339@yahoo.com

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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data can be shared after patients are made unrecognizable.
When the data will become available and for how long
Commence of accessibility will be one month after results publishment.
To whom data/document is available
All individuals can send requests to access data.
Under which criteria data/document could be used
There are no conditions for access to the results.
From where data/document is obtainable
Contact us Fatemeh Abdi abdi_201339@yahoo.com
What processes are involved for a request to access data/document
The results will be sent after receiving a request of need for this study within a week.
Comments