Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The effect of low level laser therapy at canine movement in fixed orthodontic treatment among adult

Protocol summary

Study aim

This study was carried out to answer the question whether low - level laser therapy can affect the acceleration of canine movement during a fixed orthodontic movement. If the response is positive, the length of orthodontic treatment will decrease and thus the bad effects of long - term treatment such as gingival recession, root resorption, tooth decay will be reduced.

Design

Randomized clinical trial with intervention and placebo group and split mouth design, parallel group and single blind. Randomization was done by flipping a coin with 15 patients.

Settings and conduct

The study will evaluate adult patients who receive fixed orthodontic treatment and need bilateral extractions of maxillary first premolars. After alignment and in canine retraction phase, low level laser therapy will apply in 3weeks intervals. Results will evaluate after 12weeks by intra oral scanner.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age above 18, presence of all permanent maxillary teeth except third molar,requiring of maxillary premolar extraction at both sides, the possibility of ligating the brackets to all maxillary teeth, absence of any systemic disease, good oral hygiene. Exclusion criteria: severe dental displacement (such as ectopic canine) and patients who report taking drug during treatment, any problem with the spring, brackets debonding, irregular visits.

Intervention groups

1) Intervention group: low level laser irradiation canine area at intervention side 2) control group: non irradiation at control side

Main outcome variables

Rate of canine movement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221018056237N1**
Registration date: **2022-11-02, 1401/08/11**
Registration timing: **prospective**

Last update: **2022-11-02, 1401/08/11**
Update count: **0**

Registration date

2022-11-02, 1401/08/11

Registrant information

Name

Fatemeh Shirini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4411 0127

Email address

aisashirini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-22, 1401/09/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of low level laser therapy at canine movement in fixed orthodontic treatment among adult

Public title
The effect of low level laser therapy in fixed orthodontic treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient should be older than 18 years Patient should have all permanent teeth (except third molar) There should be a possibility of placing brackets to all of the maxillary teeth Requiring extraction of premolars bilaterally in the maxillary arch Patient should have good oral hygiene
Exclusion criteria:
History of orthodontic treatment Presence of systemic disease Severe dental displacement
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
One side of the mouth is the intervention group and laser radiation will be done and the other side of the mouth is the control group.
Randomization (investigator's opinion)
Randomized
Randomization description
The design of the study is split mouth and the side of the intervention (laser radiation) and control side (placebo) in the mouth will be determined by simple randomization .The random sequence will be carried out by an independent person by flipping the coin .The side of the radiation and the non - radiation for each patient will be placed in a letter and will be opened directly before the laser irradiation starts .
Blinding (investigator's opinion)
Single blinded
Blinding description
The participants (patients) are completely unaware which side, laser will be radiated and which side is placebo.
Placebo
Used
Assignment
Parallel
Other design features
split mouth design

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the Dental branch of Tehran Azad Islamic University
Street address
No9, Dental branch of Islamic Azad University, 9th Neyestan, Pasdaran Ave, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1946853314
Approval date
2022-10-03, 1401/07/11
Ethics committee reference number
IR.IAU.DENTAL.REC.1401.080

Health conditions studied

1

Description of health condition studied
Low level laser therapy and canine movement during fixed orthodontic treatment
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Rate of canine movement
Timepoint
T0 (before laser therapy), after 6weeks, after 9weeks, after 12 weeks
Method of measurement
Intra oral scanner

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After alignment of teeth, in retraction phase, at intervention side, irradiation of GA-AL-AS diode laser (Ilase, USA) will be done with 3 weeks intervals (for 9weeks). Laser will operate at 940 nm wavelength in a continuous mode. Irradiation will deliver through the 0.04 cm2 diameter optical fiber tip in light contact with the oral mucosa.(5 points at buccal and 5 points at palatal). The target area will irradiate on these sites, for 3seconds in each point. (Mesial and distal to the cervical area of

the canine, Mesial and distal to the apical area of the canine, One point in the middle of the root). The power output set at 100 mW for 3 sec at each point made the cumulative of 7.5 J/cm2 energy density.

Category
Treatment - Devices

2

Description
Control group: After alignment phase laser will not irradiate at placebo side and just red marker of laser will be on.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Dental branch of Islamic Azad University Tehran Medical Sciences

Full name of responsible person
Fatemeh Shirini

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No.9, dental brcanch of Tehran Islamic Azad University, 9th Neyestan, Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Arash Azizi

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No.9, dental brcanch of Tehran Islamic Azad University, 9th Neyestan, Pasdaran Ave.

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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
Fatemeh Shirini

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be 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
Not applicable

Title and more details about the data/document
The total data will be shared. (all collected unidentified IPD)

When the data will become available and for how long
Access will start from 2023 .

To whom data/document is available
For researchers who working at academic institutions.

Under which criteria data/document could be used
In order to use in the scientific research, data can be used.

From where data/document is obtainable
Fatemeh shirini 00989351513752 aisashirini@gmail.com

What processes are involved for a request to access data/document
After submitting the request, it will be answered at the earliest possible time.

Comments