

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 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**

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**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/cm<sup>2</sup> 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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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Dr. Arash Azizi

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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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**Contact**

**Name of organization / entity**

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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**