

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of intra-oral LED device and low level laser therapy on the rate of orthodontic maxillary canine movement compared with control group: a randomized clinical trial

Protocol summary

Study aim

assessment of the effect of low level laser therapy & LED light on the rate of orthodontic maxillary canine movement

Design

randomized clinical trial with control group, three arm parallel , with blinded outcome assessor

Settings and conduct

Hamadan university of medical sciences, dental school canine retraction with coil spring and investigating the effect of biolight and laser therapy on the rate of tooth movement control group was blinded by a similar light device with a protective coating

Participants/Inclusion and exclusion criteria

Inclusion criteria: orthodontic treatment plan that needs extraction of maxillary first premolar unilaterally or bilaterally, presence of maxillary canine, second premolar and first molar at the side of extraction of first premolar exclusion criteria: canine root dilacerations, long-term consuming nonsteroidal anti inflammatory drugs and hormonal supplements, parafunctional habits, crossbite in canine area, poor periodontal health, pregnancy and lactating, history of previous fixed orthodontic treatment

Intervention groups

Intervention group number one: Low-level laser-therapy with Ga Al As laser with a wavelength of 810 nm four times in two months Intervention group number 2: using biolight device 5 minutes a day throughout the study course control group: using a similar light device with a protective coating four times in two months

Main outcome variables

rate of tooth movement, pain, tooth rotation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120220009086N4**

Registration date: **2019-06-01, 1398/03/11**

Registration timing: **prospective**

Last update: **2019-06-01, 1398/03/11**

Update count: **0**

Registration date

2019-06-01, 1398/03/11

Registrant information

Name

Nasrin Farhadian

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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farhadian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-10, 1398/03/20

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of intra-oral LED device and low level laser therapy on the rate of orthodontic maxillary canine movement compared with control group: a randomized clinical trial

Public title
Investigating the effect of intra-oral LED device and low level laser therapy on the rate of orthodontic maxillary canine movement compared with control group: a randomized clinical trial

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 orthodontic treatment plan that needs extraction of maxillary first premolar unilaterally or bilaterally
 presence of maxillary canine, second premolar and first molar at the side of extraction of first premolar
Exclusion criteria:
 canine root dilaceration long-term consuming nonsteroidal anti inflammatory drugs a and hormonal supplements parafunctional habits crossbite in canine area poor periodontal health pregnancy and lactating history of previous fixed orthodontic treatment

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are divided into 4 classes (gender-based and bracket-based) randomized block randomization methods. The size of the blocks is variable and is determined by the software. This randomization is coordinated by an individual outside the research team in all cases.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are blinded to intervention. Patients in the control group use a light-curing device with a protective coating in place of radiation, and radiation is done on days 0, 3, 30, and 60 according to the laser protocol. In this research, the person who collects the data, as well as the statistical advisor, are not aware of the allocation of groups, LED lasers and controls.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamadan University of Medical Sciences

Street address

in front of Mardom park, Shahid Fahmideh street, Hamadan

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hamadan

Province

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6517838741

Approval date

2019-05-06, 1398/02/16

Ethics committee reference number

IR.UMSHA.REC.1398.079

Health conditions studied

1

Description of health condition studied

Anomalies of tooth position of fully erupted teeth

ICD-10 code

M26.3

ICD-10 code description

Anomalies of tooth position of fully erupted tooth or teeth

Primary outcomes

1

Description

rate of tooth movement

Timepoint

at start of study, 1,2 and 3 months after intervention

Method of measurement

3D scanner and software

2

Description

pain

Timepoint

two weeks after intervention

Method of measurement

modified McGill questionnaire

3

Description

rotation of the canine

Timepoint

at start of study, 1,2 and 3 months after intervention

Method of measurement

3D scanner and software

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: Laser therapy is performed using the China Gigaa laser machine (dental diode laser Gigaa). The laser used is Ga Al As laser with a wavelength of 810 nm and a power of 100 μ W. Diameter of laser tip in contact with tissue is 3.1 mm. Energy density is 4 Jules per square centimeter. Therapy is performed on days 0 and 3 and then on the day of spring activation (monthly) for 4 months (days 0, 3, 30 and 60) for 2 months. The laser is projected to 3 points at the buccal surface of the canine teeth, a point in the cervical, one point in the apical region, and one point in the middle region of root, at each point for 3 seconds. Similarly, 3 regions on the palatal surface of the canine also will be irradiated.

Category

Treatment - Devices

2**Description**

Intervention group2: The patients are trained in this group and they are advised to use the biolight device for 5 minutes everyday for two months. This intra-oral LED device is made up of 640 nm wavelength and 20 mw / cm² power diodes. The device consists of 2 pairs of LEDs on the right or left that are located in the canine area of the tooth space.

Category

Treatment - Devices

3**Description**

Control group: For patients in the control group, a similar light device with a protective coating is used , and radiation is performed on days 0, 3, 30 and 60 according to the laser protocol.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hamadan university of medical sciences

Full name of responsible person

Amirfarhang Miresmaeili

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in front of Mardom park, Shahid Fahmideh street, Hamadan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Saeid Bashirian

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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

Hamedan 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**

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mozhde Borjali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Mozhde Borjali

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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
laser versus LED light groups rate of tooth movement
data set all collected deidentified IPD are to be shared
When the data will become available and for how long
starting 6 months after publication, the data will be
available for 20 years
To whom data/document is available
the data will be available only for people working in
academic institutions
Under which criteria data/document could be used

no types of analyses on the documents is allowed

From where data/document is obtainable
the preferred way of communication is via email
mozhde.borjali@yahoo.com the postal address is,
Hamadan dental school, in front of Mardom park, Shahid
Fahmideh street, Hamadan telephone number is +98 81

3838 1059 fax number is +98 81 3838 1085 the contact person is Mozhde Borjali

What processes are involved for a request to access data/document

the requests will be discussed and the data would be available in three months

Comments