Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 nonstroidal 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

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Iran (Islamic Republic of)

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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

City

hamadan

Province

Hamadan

Postal code

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 questionair

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 µW. 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 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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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
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

Academic

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
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Other areas of specialty/work
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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
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