

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The effect of LED 850 nm (intra oral) on the perception of pain and speed rate of correction of the crowded Mandibular anterior teeth : A randomized controlled clinical trial

Protocol summary

Study aim

By conducting this research and determining the effects of using an intraoral LED device with light with a wavelength of 850 nm in accelerating the improvement of crowding of the mandibular anterior teeth and the amount of pain experienced if there are positive results, this technique can be used in clinical and Used to increase speed and reduce pain in orthodontic treatments

Design

Clinical trial of a two-way blind control group using stratified block randomization method was used

Settings and conduct

Patients are selected from the special clinic of Hamadan Dental School and the person analyzing the results is blind to which group the collected information belongs to.

Participants/Inclusion and exclusion criteria

inclusion : Patients aged 15-30 years require fixed orthodontic treatment - Non-extraction treatment plan Index of Dental Irregularities Larger Equals 2 mm and Less Equals 6 mm (Lower Anterior Crowding) - Periodontal health and good oral hygiene (patients should not bleed from the gums during periodontal probe exclusion : Patients with periodontal problems, patients taking chronic drugs that affect bone metabolism (corticosteroids ...) And if patients have a bracket failure and the bracket is not replaced within a week, they will be excluded from the study.

Intervention groups

In the test group, The LED device with a wavelength of 850 nm is delivered to the patient to use it continuously for 5 minutes every day before going to bed. And charge the device once a week. In the control group, no radiation is performed.

Main outcome variables

rate of tooth movement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120220009086N5**

Registration date: **2021-11-17, 1400/08/26**

Registration timing: **prospective**

Last update: **2021-11-17, 1400/08/26**

Update count: **0**

Registration date

2021-11-17, 1400/08/26

Registrant information

Name

Nasrin Farhadian

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1835 4017

Email address

farhadian@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-31, 1400/10/10

Expected recruitment end date

2022-03-30, 1401/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of LED 850 nm (intra oral) on the perception of pain and speed rate of correction of the crowded Mandibular anterior teeth : A randomized controlled clinical trial

Public title

The effect of LED 850 nm (intra oral) on the perception of pain and speed rate of correction of the crowded Mandibular anterior teeth : A randomized controlled clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a grade of 2-6 mm with a small irregularity index are screened.

Exclusion criteria:

long-term consuming nonsteroidal anti inflammatory drugs and hormonal supplements poor periodontal health Patients will be excluded from the study if the bracket fails and the bracket is not replaced within a week.

Age

From **15 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups of control and LED as a block randomization method. Determines the order in which people are placed in groups. An envelope is selected and this person is placed in one of these groups

Blinding (investigator's opinion)

Double blinded

Blinding description

In this research, the person who collects the data, as well as the statistical advisor, are not aware of the allocation of groups, LED and controls

Placebo

Not 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

2021-10-18, 1400/07/26

Ethics committee reference number

IR.UMSHA.REC.1400.575

Health conditions studied

1

Description of health condition studied

Crowding of fully erupted teeth

ICD-10 code

M26.31

ICD-10 code description

Crowding of fully erupted teeth

Primary outcomes

1

Description

rate of tooth movement

Timepoint

At the beginning and end of the study

Method of measurement

study cast

2

Description

pain

Timepoint

two weeks after intervention

Method of measurement

modified McGill questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group": All patients in the intervention group who have a fixed orthodontic appliance in their jaws are instructed to turn on the appliance for 5 minutes daily and put it in their mouth. This intraoral LED device is made of diodes with a wavelength of 850 nm, which are located in the area of the mandibular anterior teeth. And the patient turns it on and uses it by pressing a button embedded on the device. It should be noted that this device is delivered to the patient from the first session when the brackets and wires are placed on the anterior teeth of the mandible. These patients are visited on a monthly basis until the anterior crowding reaches below 1 mm, which is the end of use the device in this group.

Category

Treatment - Devices

2

Description

Control group: All patients with fixed orthodontic appliance in the mandible. These patients are not given any LED devices and are treated normally. These patients are visited monthly until the crowding in the anterior mandibular region reach below 1 mm.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamadan University of Medical Sciences

Full name of responsible person
Nasrin Farhadain

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in front of Mardom park, Shahid Fahmideh street,
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Web page address
<http://dentistry.umsha.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamedan University of Medical Sciences

Full name of responsible person

Saied Bashirian

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bashirian@umsha.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Hamadan 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

Yousef Ahmadpour

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Yousef Ahmadpour

Position

Resident

Latest degree

Medical doctor

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

Dental velocity data set can be shared in the light data group compared to the potential control group after unidentifiable individuals

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 chrika2020@gmail.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 yousef ahmadpour

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

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