Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Sep 2026

Evaluation of low level laser therapy on acceleration of anterior teeth movement in the first phase of orthodontic treatment among patients referred to orthodontic department of dentistry Faculty

Protocol summary

Study aim
Use a non-invasive method to accelerate tooth movement and shorten orthodontic treatment time

Design
Clinical trial with control group with parallel groups, one-way blind, third phase of the trial, randomized on 14 patients by block randomization method with 4 blocks.

Settings and conduct
This study is performed on patients undergoing orthodontic treatment at the School of Dentistry. The anterior teeth of one side of the patient are irradiated with a low-level diode laser, which emits an infrared wave with a wavelength of 810 nm. A laser tip is placed on the other side of the patient's mouth, but laser radiation is not performed. The patient does not know which side is irradiated. Laser therapy is performed in each session until the anterior teeth are fully aligned. The final result is evaluated as the difference in the time of alignment of the anterior teeth on both sides.

Participants/Inclusion and exclusion criteria
Patients with permanent teeth in the age range of 15 to 30 years who need comprehensive orthodontic treatment. With a degree of dental malformation, Little is larger than 4 mm and less than 8 mm, and the treatment plan is without tooth extraction. Patients who are systemically healthy. They have good oral health and healthy periodontal status. Exclsuion criteria: Uncontrolled periodontal problems with bone resorption Gingival resorption greater than 2 mm Smoker Bone metabolism is altered as a result of illness or medication Physical or mental disability Pregnancy

Intervention groups
1- Intervention group: One side of the patient, right or left, is randomly selected as the experimental group and is regularly irradiated with laser during orthodontic treatment. 2- Control group: A laser tip is placed on the other side of the patient's mouth, but laser radiation is not performed.

Main outcome variables
Accelerate tooth movement in orthodontic treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211203053265N1**
Registration date: **2022-02-26, 1400/12/07**
Registration timing: **prospective**

Last update: **2022-02-26, 1400/12/07**
Update count: **0**

Registration date
2022-02-26, 1400/12/07

Registrant information

Name
Mahboobe Hoseini

Name of organization / entity

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Iran (Islamic Republic of)

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+98 13 3373 7193

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-03, 1401/01/14

Expected recruitment end date
2022-10-22, 1401/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of low level laser therapy on acceleration of anterior teeth movement in the first phase of orthodontic treatment among patients referred to orthodontic department of dentistry Faculty

Public title
Evaluation of low level laser therapy on acceleration of anterior teeth movement in the first phase of orthodontic treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with permanent dentition aged between 15 to 30 years old that need orthodontic treatment. Little Irregularity Index score between 4 to 8 millimeters Healthy systemic patients Good oral hygiene and healthy periodontal status
Exclusion criteria:
Uncontrolled periodontal problems with bone loss Gum recession more than 2 millimeters Smoking Altered bone metabolism due to disease or drug use Physical or mental disability Pregnancy
Age
From **15 years** old to **30 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **28**
More than 1 sample in each individual
Number of samples in each individual: **2**
The patient's central, lateral, and canine teeth are on the right or left side
Randomization (investigator's opinion)
Randomized
Randomization description
To randomize the treatment between the left and right mouth, a block randomization method with 4 blocks will be used (block size: 4, actual list length: 14). Considering the time of entry into the study, group A indicates receiving laser treatment on the right side and group B indicates receiving laser treatment on the left side of the mouth and the other side is considered as control. It is an individual randomization unit. Randomization tool is SAS statistical software version 9. How to build a randomization sequence: Block ID, block size, sequence within the block, treatment for example: • 1, 4, 1, Group B. • 1, 4, 2, Group A. ....
Blinding (investigator's opinion)
Single blinded
Blinding description
patients are unaware about the test group because tip of the device will be put on the control side but radiation will not be done.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Ahmadzade Ave, Amini Alley, 107 apartment
City
Rasht
Province
Guilan
Postal code
4174734681
Approval date
2021-11-25, 1400/09/04
Ethics committee reference number
IR.GUMS.REC.1400.407

Health conditions studied

1

Description of health condition studied
Anomalies of tooth position
ICD-10 code
K07.3
ICD-10 code description
K07.3 Anomalies of tooth position

Primary outcomes

1

Description
Accelerate tooth movement in orthodontic treatment
Timepoint
At the end of the time the anterior teeth become aligned
Method of measurement
Number of days for the patient's teeth to be aligned

Secondary outcomes

1

Description

Reduce pain during orthodontic treatment

Timepoint

After each replacement of the archwire. Normally 3 times during treatment

Method of measurement

After each archwire replacement, each patient's pain is measured on a visual analogue scale 24 hours after the visit.

Intervention groups

1

Description

Intervention group: Central, lateral and canine teeth on one side of the patient are exposed to laser radiation. The laser in this study is a low-power gallium arsenide diode (model THOR LX2) that emits an infrared wave with a wavelength of 810 nm. The radiation is continuous with a power of 200 mW. Laser therapy is repeated on days 3, 7, 14 and every month to achieve complete alignment and leveling of the anterior teeth.

Category

Treatment - Other

2

Description

Control group: Central, lateral and canine teeth on the opposite side of the patient. To blind the tip of the laser device is placed on the teeth of this part, but laser radiation is not done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

dentistry faculty of Guilan university of medical science

Full name of responsible person

Faeghe Gholinia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Faeghe Gholinia

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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
Undecided - It is not yet known if there will be 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
Evaluation of low level laser therapy on acceleration of anterior teeth movement in the first phase of orthodontic treatment among patients referred to orthodontic department of Guilan dentistry Faculty
When the data will become available and for how long
Start the access period 6 months after publishing the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Researchers working in academic institutions
From where data/document is obtainable
gholiniaf@gmail.com
What processes are involved for a request to access data/document
6 months
Comments