Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Low Level Laser Irradiation on rate of relapse of mandibular incisors after fixed orthodontic treatment by extraction

Protocol summary

Study aim
Evaluation of Low Level Laser Irradiation on rate of relapse of mandibular incisors after fixed orthodontic treatment by extraction

Design
Clinical trials with a control group, with parallel groups, single-blind, randomized.

Settings and conduct
The study will be conducted on patients referring to the Department of Orthodontics, School of Dentistry, Babol University of Medical Sciences, Babol, Iran, who need orthodontic treatment. Allocation to groups will be done randomly and for each treatment group, 10 samples and a total of 20 samples will be considered. Outcome evaluator of this study will be blind (single-blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range 12 to 18 years, Average Crowding Rate (5-9 mm), similar treatment (Extraction), Good oral hygiene (index plaque and gingival index zero or one), Signature of consent form. Non-inclusion criteria: Consumption of medicine that interrupted bone metabolism, contraindication for laser therapy eg, pregnancy, Patients with systemic diseases, The teeth have more than 45 degrees rotation, Patients with gingival inflammation or periodontal problems and those with proximal caries, deep caries extending to the cemento-enamel junction.

Intervention groups
Intervention group: Patients undergoing orthodontic treatment during the dental relapse period are exposed to GaAlAs laser irradiation. The low-level laser irradiation will be performed thrice a week for 4 weeks. Control group: Orthodontic treatment alone will be done (no intervention to minimize relapse will be performed.).

Main outcome variables
Bone Density, Percentage of relapse

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200208046415N1**
Registration date: **2020-04-06, 1399/01/18**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-06, 1399/01/18**
Update count: **0**

Registration date
2020-04-06, 1399/01/18

Registrant information

Name
Rahil Mirzaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-12, 1398/07/20

Expected recruitment end date
2020-05-21, 1399/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of Low Level Laser Irradiation on rate of relapse of mandibular incisors after fixed orthodontic treatment by extraction

Public title
The effect of Low Level Laser Irradiation on rate of relapse of mandibular incisors
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age range of 12 to 18 years old Average Crowding Rate (5-9 mm) Similar treatment (Extraction) Good oral hygiene (index plaque and gingival index zero or one) Signature of consent form
Exclusion criteria:
Consuming medicine that interrupted bone metabolism Patients with conditions for which laser therapy will be contraindicated (eg, pregnancy) Patients with systemic diseases The teeth have more than 45 degrees rotation Patients with gingival inflammation or periodontal problems and those with proximal caries, deep caries extending to the cemento-enamel junction.
Age
From **12 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly assigned to two treatment groups using the randomized block method and the free site www.randomization.com will be used to generate the allocation sequence. The obtained sequence will be written on separate sheets and placed in sealed envelopes and will be given to the principal investigator for the study.
Blinding (investigator's opinion)
Single blinded
Blinding description
The outcome measurer is different from whom that cures patients.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Babol University of Medical Sciences
Street address
Ganjafrooz Ave.
City
Babol
Province
Mazandaran
Postal code
4717643633
Approval date
2019-12-29, 1398/10/08
Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.280

Health conditions studied

1

Description of health condition studied
Orthodontic relapse
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Bone Density
Timepoint
Before low level laser irradiation, and 4 weeks after low level laser irradiation
Method of measurement
Periapical radiography

2

Description
The percentage of relapse
Timepoint
1, 2, 3 and 4 weeks after low level laser irradiation
Method of measurement
The percentage of relapse will be also calculated relative to the initial angle of rotation according to the following formula: the amount of relapse/ the initial degree of rotation *100

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients undergoing orthodontic treatment during the dental relapse period are randomly

exposed to GaAlAs laser irradiation. The laser probe will be positioned in contact with gingival tissue in the coronal third of the root, and the irradiation will be performed on 4 points around the tooth, including mesiobuccal, distobuccal, mesiolingual, and distolingual areas. The low-level laser irradiation will be performed thrice a week for 4 weeks.

Category

Treatment - Devices

2

Description

Control group: Orthodontic treatment alone (no intervention to minimize relapse will be performed.)

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthodontic department of Babol dental faculty

Full name of responsible person

Rahil Mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Vali alah Arash

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Vali alah Arash

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

Contact
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Rahil Mirzaei
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Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available