

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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)

##### Phone

+98 11 3232 5406

##### Email address

r.mirzaei@mubabol.ac.ir

##### 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**

Vali alah Arash

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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**

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 updating data

### Contact

**Name of organization / entity**  
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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