Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of canine retraction using Er:Yag and Photobiomodulation in patients undergoing orthodontic treatment

Protocol summary

Study aim
Comparison of canine retraction speed in patients undergoing orthodontic treatment using photobiomodulation therapy and Er:YAG laser

Design
A controlled, double-blind, randomized, parallel-group clinical trial, on 24 patients. Randomized blocks will be used for randomization.

Settings and conduct
Healthy patients aged 14 to 27 years who require bilateral maxillary first premolars to be extracted for orthodontic treatment will be enrolled in the study. The location of data collection will be a private orthodontist's office in Sari. Patients will be randomly divided into three groups and will be treated with low-level laser, erbium-YAG laser, and low-level laser combined with erbium-YAG laser. The opposite quadrant in each patient will be considered as a control. The control quadrant will be selected randomly by coin toss. This study will be double-blinded and the person recording the changes and the statistical consultant will not be aware of the study groups.

Participants/Inclusion and exclusion criteria
In this study, the study population will be comprised of healthy patients aged 14 to 27 years who require extraction of bilateral maxillary first premolars due to orthodontic treatment.

Intervention groups
1. First intervention group: In this group, low-level laser is irradiated twice a week for four weeks 2. Second intervention group: In this group, erbium laser is irradiated twice a week for four weeks 3. Third intervention group: In this group, both types of intervention with low-level laser and erbium are irradiated simultaneously twice a week for four weeks 4. Control group: The opposite quadrant of each patient will be considered the control group and no additional intervention will be performed on that side.

Main outcome variables
canine retraction rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250526065916N1**
Registration date: **2025-07-27, 1404/05/05**
Registration timing: **registered_while_recruiting**

Last update: **2025-07-27, 1404/05/05**
Update count: **0**

Registration date
2025-07-27, 1404/05/05

Registrant information

Name
Melika Mollaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of canine retraction using Er:Yag and Photobiomodulation in patients undergoing orthodontic treatment

Public title
Investigating the effect of laser on tooth movement rate during orthodontic treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age of 14 to 27 years old Healthy patients with appropriate oral hygiene and periodontal condition Class II div I individuals who require bilateral maxillary first premolar extraction followed by canine retraction. no history of orthodontic treatment

Exclusion criteria:
presence of systemic diseases Patients with dental phobia

Age
From **14 years** old to **27 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
The simple randomization method will be used with random blocks. Using Stata software, 8 blocks of 3 will be randomly generated. Then, a block will be randomly selected from the list and people will be assigned to groups based on the block.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted in a double-blind manner. The patients and the person administering the interventions will be aware of the patient groups. However, the person who will follow up the patients and record the changes that occur, as well as the statistical consultant who will be responsible for comparing the results, will not be aware of the study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences

Street address
Deputy for Research and Technology Building, Moalem Square, Sari, Mazandaran province

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Sari

Province
Mazandaran

Postal code
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Approval date
2025-04-06, 1404/01/17

Ethics committee reference number
IR.MAZUMS.REC.1404.025

Health conditions studied

1

Description of health condition studied
orthodontic issues

ICD-10 code
M26.212

ICD-10 code description
Malocclusion, Angle's class II

Primary outcomes

1

Description
canine retraction rate

Timepoint
Before intervention, 1 month after intervention, 2 months after intervention

Method of measurement
Orthodontic software package

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Low-level laser therapy (LLLT). Low-level laser therapy (LLLT) will be performed twice a week for four weeks using a continuous-wave mode laser (EPIC X, Biolase, USA) with the following characteristics: 940 nm, power 200 mW, and tip cross-section area 4 cm2 with an energy density of 4 J/cm2

Category
Treatment - Other

2

Description
Intervention group 2: Er:YAG. In this group, ER:YAG laser (WaterLase, Biolase, USA) with MT4 gold handpiece (diameter: 400 microns, length: 6 mm) will be applied twice a week for four weeks.

Category
Treatment - Other

3

Description
Intervention group 3: Low-level laser therapy (LLLT) + ER:YAG laser. In this group, both methods mentioned in the first and second intervention groups will be applied simultaneously according to the protocols mentioned in the first and second intervention groups. In this group, low-level laser therapy (LLLT) is performed via a continuous-wave mode laser (EPIC X, Biolase, USA) with the following characteristics: 940 nm, power 200 mW, and tip cross-section 4 cm2 with an energy density of 4 J/cm2. Then, ER:YAG (WaterLase, Biolase, USA) is applied with a gold handpiece MT4 (diameter: 400 microns, length: 6 mm). Both lasers will be applied twice a week for four weeks.

Category
Treatment - Other

4

Description
Control group: In all groups, the opposite quadrant will be considered as the control. In fact, out of 32 participants, one side of the patient's jaw will be considered as the intervention and the opposite side as the control. The choice of the control or model side will be determined by a coin toss. There will be no intervention on the control side.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Touba Dental Clinic

Full name of responsible person
Dr. Avideh Maboudi

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Tooba Dental Clinic, Khazar Boulevard, Sari, Mazandaran province

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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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Grant name
Deputy for Research of Mazandaran University of Medical Sciences

Grant code / Reference number
23223

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

Title of funding source
Mazandaran 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
Mazandaran University of Medical Sciences

Full name of responsible person
Dr. Avideh Maboudi

Position
Associate professor

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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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