Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of piezoincision and photobiomodulation on canine retraction rate in patients undergoing orthodontic treatment

Protocol summary

Study aim
Comparison of the effect of piezoincision and photobiomodulation on canine retraction rate in patients undergoing orthodontic treatment

Design
A randomized, double-blind, parallel-group, controlled clinical trial on 32 patients will use randomized blocks for randomization.

Settings and conduct
Healthy patients aged 14 to 27 years who require bilateral maxillary first premolars extraction due to orthodontic treatment will be included in the study. The collection location will be Tooba Dental Clinic located in Sari. Patients will be randomly divided into four groups and will be treated with low-level laser, piezoincision, and a combination of both interventions. The control group will receive conventional orthodontic treatment and will not receive any additional intervention. Patients will be randomly selected through random blocks. This study will be double-blind and the person recording the changes and the statistical consultant will not be aware of the study groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 14 and 27 years old, Good periodontal status and oral hygiene, Class II, div I individuals requiring bilateral upper first premolar extraction, No history of orthodontic treatment Exclusion criteria: Presence of systemic disease, Presence of dental phobia

Intervention groups
1. The first intervention group: In this group, low-power laser is irradiated twice a week for four weeks. 2. The second intervention group: In this group, the area between teeth 3 and 5 will be drilled to a depth of 3 mm in the bone using piezoincision. 3. The third intervention group: In this group, the area in question will first be drilled to a depth of 3 mm with piezoincision, and then low-power laser will be applied twice a week for four weeks. 4. The control group: No additional intervention will be performed on the patients

Main outcome variables
Canine retraction rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250526065916N2**
Registration date: **2025-10-21, 1404/07/29**
Registration timing: **prospective**

Last update: **2025-10-21, 1404/07/29**
Update count: **0**

Registration date
2025-10-21, 1404/07/29

Registrant information

Name
Melika Mollaei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3324 4014

Email address
melika.mollaei.7@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-23, 1404/08/01

Expected recruitment end date
2026-04-21, 1405/02/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of piezoincision and photobiomodulation on canine retraction rate in patients undergoing orthodontic treatment

Public title

Comparing the effects of laser and surgery in accelerating orthodontic treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 14 to 27 Healthy patients with good oral hygiene and periodontal status 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 Presence of dental phobia

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method will be simple and using random blocks. Using SATA software, 8 blocks of 3 will be randomly generated. Then, 1 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 style. The patients and the administrator will be aware of the study groups; however, the person who will follow up the patients as well as the statistical consultant, 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 of research and technology building, Moalem Square, Mazandaran Province, Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Approval date

2025-09-23, 1404/07/01

Ethics committee reference number

IR.MAZUMS.REC.1404.310

Health conditions studied

1

Description of health condition studied

Orthodontic Problems

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: Photobiomodulation therapy: In the first intervention group, low-level laser therapy was performed twice a week for four weeks via a continuous-wave mode laser (EPIC X, Biolase, USA) with the following characteristics: 940 nm, power 200 mW. A tip cross-section of 4 cm2 with an energy density of 4 J/cm2 (16 J/cm2 for each tooth) was applied to each area for 25 seconds. The laser was applied to 4 peri-tooth areas such

as mesilingual, distolingual, distobuccal and mesiobuccal. In addition, the apical, medial and cervical parts of the canine roots in both buccal and lingual areas as well as the angles of the distobuccal and distopalatal lines were irradiated.

Category

Treatment - Other

2

Description

Intervention group 2: Piezoincision group: Due to the invasiveness of piezoincision, this procedure will be performed only once. Depending on the degree of keratinized gingiva, 1 or 2 points in the interradicular area of teeth 3 and 5 will be drilled into the bone to a depth of 3 mm using a piezotome device (Acteon, CUBE, France).

Category

Treatment - Surgery

3

Description

Intervention group 3: Piezoincision + photobiomodulation group: In this group, first, based on the degree of keratinized gingiva, 1 or 2 points in the interradicular area of teeth 3 and 5 will be drilled into the bone to a depth of 3 mm using a piezotome device (Acteon, CUBE, France). In addition, low-level laser therapy will be performed twice a week for four weeks via a continuous-wave mode laser (EPIC X, Biolase, USA) with the following characteristics: 940 nm, power 200 mW. A tip cross-section of 4 cm2 with an energy density of 4 J/cm2 (16 J/cm2 for each tooth), applied to each area for 25 seconds.

Category

Treatment - Other

4

Description

Control group: No additional intervention will be performed on these patients and orthodontic treatment will be performed using the conventional method.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tooba Dental Clinic

Full name of responsible person

Dr. Avideh Maboudi

Street address

Tooba Dental Clinic, Khazar Boulevard, Sari, Mazandaran Province

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3324 0002

Email

research@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Ahmadali Enayati

Street address

Deputy for Research and Technology Building, Moalem Square, Sari, Mazandaran Province

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3324 0002

Email

research@mazums.ac.ir

Grant name

Deputy of Research of Mazandaran University of Medical Sciences

Grant code / Reference number

۲۳۷۷۲

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

Street address

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

City

sari

Province

Mazandaran

Postal code

۴۸۱۵۷۳۳۹۷۱

Phone

+98 11 3304 4030

Email

avideh.maboudi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Melika Mollaei

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Moallem avenue

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3324 4014

Fax

Email

Melika.mollaei.7@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Melika Mollaei

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Moallem avenue

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3324 4014

Fax

Email

Melika.mollaei.7@gmail.com

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