

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effects of combined low-level laser and piezocision versus each technique separately on canine retraction

Protocol summary

Study aim

Effects of combined low-level laser and piezocision versus each technique separately on canine retraction

Design

Clinical trial with control group, with parallel groups, without blinding, randomized by block randomization method on 33 patients in 3 groups of 11 each

Settings and conduct

33 patients from Ahvaz Dental School In 3 groups: A, one side the control one side the piezocision group (once). 1-2 points in the IR area of teeth 3 and 5, 3 mm deep into the bone using a pizotome. group B, one side control one side diode laser group. 810 nm laser with energy 8 J and power of 0.5W performed for 16 seconds at 6 points on the buccal and lingual side of the maxilla canine on day 1 and weeks 3 and 6. In group C, one The control side the other side consider the combination of piezocision + laser radiation with the same protocol as before. After the alignment the first premolars are extracted, anchorage is maintained with a vertical stop in front of the 6 teeth, canine retraction on 17x25 ss and 150 g forces are done with a short size chain. Each session (week 3.6.9) is molded, casts are scanned, and distance between the end of the midpoint of the third rug in the palate for each side (as a fixed point) to the midpoint of the canine tooth on each side is determined to determine the extent of retraction changes. The distance from that point to the central fossa of the tooth is measured to anchorage loss.

Participants/Inclusion and exclusion criteria

Admission: Age 15 to 25, Absence of any disease and requires extraction of first premolars on both sides; No entry: Previous orthodontics and trauma while extraction

Intervention groups

Diode laser radiation group, Piezocision group and the group combines two methods In each group one side of maxilla will be consider as the control group and one side the action group.

Main outcome variables

Canine retraction rate in two maxillary quadrants

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201110049346N1**

Registration date: **2021-01-06, 1399/10/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-06, 1399/10/17**

Update count: **0**

Registration date

2021-01-06, 1399/10/17

Registrant information

Name

Rayan Chaharmahali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3447 1049

Email address

charmahali.r@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-04-21, 1400/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of combined low-level laser and piezocision versus each technique separately on canine retraction

Public title
Effects of combined low-level laser and piezocision versus each technique separately on canine retraction

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
Age range 15 to 25 years
Absence of any systemic disease and active periodontal disease
Need to extraction of the first premolars on both sides
NO Previous orthodontic treatment
It has the normal shape and structure of the canine, the second premolar and the first maxillary molar
Exclusion criteria:

Age
From **15 years** old to **25 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **33**
More than 1 sample in each individual
Number of samples in each individual: **2**
n each of the 11 participants in one of the 3 study groups, one maxilla quadrant is considered as the action group (intervention) and the other quadrant is considered as the control group.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, random sequencing is done by restricted randomization method and since the equality of the two intervention groups is very important, the permuted block randomization subgroup is used. Random allocation is concealed using opaque envelopes sealed in random sequence. In this way, based on the sample size of the research, a number of non-transparent envelopes are prepared and each random sequence is recorded on a card and the cards are placed in the envelopes in order. In order to maintain a random sequence, envelopes are numbered in the same way on the outer surface. At the beginning of the registration of participants, based on the order of entry of eligible participants to study, one of the envelopes is opened in order and its assigned group is identified. Finally, due to the split mouth of the study method, each quadrant of the patient's maxilla is assigned to the control group or the intervention is done by coin flipping (heads or tails).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahwaz Jundishapur University of Medical Sciences

Street address

Golestan. Khordad St., between Esfand St. and Iqbal St., Avisa Complex, Unit 5

City

Ahwaz

Province

Khouzestan

Postal code

6451766555

Approval date

2020-10-19, 1399/07/28

Ethics committee reference number

IR.AJUMS.REC.1399.612

Health conditions studied

1

Description of health condition studied

Orthodontic patient with treatment plan for extraction of 4 maxillary teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Canine retraction rate in two maxillary quadrants using orthodontic piezo, laser and laser + piezo

Timepoint

In the samples of piezocision operation, measurements are made at the beginning of the study (before the intervention), 3, 6 and 9 weeks after the intervention on both control and operation sides (the piezocision operation is performed only once.) In the sample Laser measurements are performed at the beginning of the study, at weeks 3, 6 and 9. (The laser is irradiated on the first day and weeks 3 and 6.) In the combination group, 2 measurement methods are similar to the previous two methods at the beginning, week 3, 6 and 9 are performed. (In this group, the piezocision operation is performed once on the first day and the laser is irradiated on the first day and weeks 3 and 6).

Method of measurement

Scan of casts at 3, 6 and 9 weeks and measuring the amount of movement compared to the initial time

Secondary outcomes

empty

Intervention groups

1

Description

The group prepared by piezocision surgery. 11 subjects were randomly selected and in each individual, a maxilla quadrant was randomly selected one week after extraction of the first maxillary premolars and 1-2 points in the area. Between the roots of teeth 3 and 5 are determined based on the amount of keratinized gums and inserted to a depth of 3 mm into the bone using a piezoelectric device (Acteon, CUBE, France) and piezocision surgery will be performed. The operation is performed only once. The type of movement considered is the movement of the canine tooth alone, so the connection of teeth 5 and 6 and the upper incisors will be done together and a vertical stop will be placed in front of tooth 6 to maintain anchorage. Standard canine retraction is performed on 17x25 stainless steel wires by applying standard forces of 150 g using force gauge (COREX, HAAG-STREIT, Switzerland) using elastomeric China (American Orthodontics, Sheboygan, WI, USA) short size. On the first day and weeks 3, 6 and 9, molding will be done to measure the amount of retraction.

Category

Diagnosis

2

Description

Control group: The group prepared by the piezogen. Another quadrant of the maxilla is considered as the control group, and the wire and crease are placed in the same way to finally measure and compare the amount of retraction in millimeters on both sides.

Category

Diagnosis

3

Description

Intervention group: Laser irradiation group. 11 subjects were randomly selected and each maxillary quadrant was randomly selected one week after extraction of the first maxillary premolars. 810 nm laser radiation (dentaLase, QuickLase, Great Britain).) With energy of 8 joules and power of 5 / . Watt will be performed for 16 seconds at 6 points on the buccal side and 6 points on the lingual side (two points on the cervical, two points on the middle region and two points on the apex) of the maxilla canine on the first day and weeks 3 and 6. The previous method is inserted and the molding is similar to the previous method.

Category

Diagnosis

4

Description

control group: Laser radiation group. Another quadrant of the maxilla is considered as the control group, and the wire and crease are placed in the same way to finally measure and compare the amount of retraction in millimeters on both sides.

Category

Diagnosis

5

Description

Intervention group: Combination group of laser radiation and piezocision operation. 11 subjects were randomly selected and a maxillary quadrant in each individual was randomly selected one week after extraction of the first maxillary premolars. The piezocision operation and the first laser session are applied simultaneously on the selected side. And wire and crease will be placed and molding will be done similar to the previous two methods.

Category

Diagnosis

6

Description

Control group: Laser irradiation and piezocision operation group. Another quadrant of the maxilla is considered as the control group, and the wire and crease are placed in the same way to finally measure and compare the amount of retraction in millimeters on both sides.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz Dental School

Full name of responsible person

rayan chaharmahali

Street address

Golestn.dey avenue

City

Ahwaz

Province

Khouzestan

Postal code

6451766555

Phone

+98 61 3447 1049

Email

charmahali.r@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Morteza Gooran

Street address

Golestan.esfand avenue

City

Ahwaz

Province

Khouzestan

Postal code

6451766555

Phone

+98 61 3447 1049

Email

charmahali.r@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Rayan Chaharmahali

Position

رزیډنت ارتودنسی

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Golestan.Dey avenue

City

Ahwaz

Province

Khouzestan

Postal code

6451766555

Phone

+98 61 3447 1049

Email

charmahali.r@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Rayan Chaharmahli

Position

Orthodontics resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Golestan,dey avenue

City

Ahwaz

Province

Khouzestan

Postal code

6451766555

Phone

+98 61 3447 1049

Email

charmahali.r@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Rayan Chaharmahali

Position

Orthodontics resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Golestan,dey avenue

City

Ahwaz

Province

Khouzestan

Postal code

6451766555

Phone

+98 61 3447 1049

Email

charmahali.r@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