

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Maxillary canine retraction changes with self-ligating ceramic brackets versus metal-slot ceramic brackets in the patient that need to extract two maxillary premolars: A clinical trial

Protocol summary

Study aim

Comparison of changes in canine maxillary retraction with ceramic and self-ligating ceramic bracket in split-mouth (clinical trial study)

Design

The clinical trial consists of the controlled group, which bond with common ceramic brackets and an intervention group with a self-ligating ceramic brackets support by studying a 16 of people samples deemed statistically representative, a randomized, single-blind study.

Settings and conduct

Pay attention to beauty and esthetic and lake of a study of ceramic brackets. We would like to study this one in the faculty of orthodontics of Ahwaz. The teeth are bonded randomly and one-way blind to patients in either self-ligating ceramic bracket or control group with conventional ceramic brackets

Participants/Inclusion and exclusion criteria

Entry requirements: Patients requiring two first premolar extraction in their treatment plan. Central maxillary incisors are aligned. The patient has written consent to participate in the study. In case of non-arrival: have a systemic illness or are taking drugs that interfere with orthodontic treatment. The patient will not be able to tolerate long-term meetings. The patient has panoramic radiography at the onset of the treatment of periapical lesions and root anomalies

Intervention groups

Groups: Random Team, canines left or right of self-ligating ceramic brackets. Control group: The rhyming group, their right or left canines teeth, is a conventional ceramic bracket.

Main outcome variables

Canine retraction: Canine movement to distal. Canine rotation: Canine rotation around its long axis during a spin to distal loss of anchorage: Movement of second premolar teeth and first and second molars to mesial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180710040414N1**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **prospective**

Last update: **2018-09-04, 1397/06/13**

Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Nasim Ghorani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-06, 1397/06/15

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Maxillary canine retraction changes with self-ligating ceramic brackets versus metal-slot ceramic brackets in the patient that need to extract two maxillary premolars: A clinical trial

Public title

Maxillary canine retraction changes with self-ligating ceramic brackets versus metal-slot ceramic brackets : A split-mouth randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who require two first premolar extraction in their treatment plan. Central Maxillary incisor must become align Patient Informed consent is the process by which a subject voluntarily confirms his/her willingness to participate in a study.

Exclusion criteria:

have a systemic illness or are taking drugs that interfere with orthodontic treatment. The patient will not be able to tolerate long-term meetings. The patient has panoramic radiography at the onset of the treatment of periapical lesions and root anomalies.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **16**

More than 1 sample in each individual

Number of samples in each individual: **2**
right canines and left canines

Randomization (investigator's opinion)

Randomized

Randomization description

In order to remove the non-selection error of the ceramic and ceramic self-adhesive bracket in the right or left canine teeth, a simple randomization method was used to extract random numbers from a third person using the website www.randomizer.org. Hidden methods. The allocation concealment of this test is that simultaneously with the patient's referral for a bonding of brackets to the right or left tooth, extraction of a random number by a third person, and the researcher was told which bracket would be placed on which side.

Blinding (investigator's opinion)

Single blinded

Blinding description

All steps of treatment are explained to the patient and consent to treatment is the principle that a person must give permission before they receive any type of treatment, test or examination. Consent from a patient is needed regardless of the procedure. The patient does not know which tooth has a bracket. Using randomization

is a reliable method of creating homogeneous treatment groups, without involving any potential biases or judgments. Groups are also identified by letters before being analyzed statistically and in this way, the parser will not know which groups are associated with which slice, etc.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of ahvaz jundishapur university of medical sciences

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Ahvaz Jundishapur University of Medical Sciences,
Olompezeshki Blvd, Ahvaz Town

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Khuzestan

Postal code

6135715794

Approval date

2018-06-23, 1397/04/02

Ethics committee reference number

IR.AJUMS.REC.1397.254

Health conditions studied**1****Description of health condition studied**

Maxillary canine retraction

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Maxillary canine rotation

ICD-10 code**ICD-10 code description****3****Description of health condition studied**

Anchorage loss

ICD-10 code**ICD-10 code description**

Primary outcomes

1

Description

Canine Retraction

Timepoint

3 months after force application

Method of measurement

Electronic Boley Gauge

2

Description

Canine Rotation

Timepoint

3 months after force application

Method of measurement

protractor

3

Description

anchorage loss

Timepoint

3 months after force application

Method of measurement

Electronic Boley Gauge

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group whose maxillary left or right canine attached ceramic self-ligating braces

Category

Treatment - Devices

2

Description

Control group: A group whose maxillary left or right canine attached common ceramic braces

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Jundishapur University of Medical Sciences
Faculty of Dentistry

Full name of responsible person

Ghorani Nasim

Street address

Ahvaz Jundishapur University of Medical Sciences
Faculty of Dentistry, Olompezeshki Blvd, Ahvaz Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr Ahmad Badvi

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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

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

Ghorani Nasim

Position

Orthodontic Resident

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