Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 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)

Phone

+98 31 3627 5341

Email address

nasimghorani@yahoo.com

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

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

City
Ahvaz

Province
Khouzestan

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
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 31 3627 5341
Email
nasimghorani@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Ahmad Badvi
Street address
Ahvaz Jundishapur University of Medical Sciences, Olompezeshki Blvd, Ahvaz Town
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 2414
Fax
+98 61 3336 1544
Email
itc@ajums.ac.ir
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

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

City
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Province
Khouzestan

Postal code
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Phone
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Email
nasimghorani@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

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Email
nasimghorani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

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Email
nasimghorani@yahoo.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