Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Root length evaluation after orthodontic treatment in immature teeth

Protocol summary

Study aim
Evaluate relationship between orthodontic tooth movement and root development

Design
In this study, 32 patients indicated for fixed orthodontic treatment considering inclusion criteria will be selected. Second premolar teeth in both sides of mandible enter to case and control group by random table.

Settings and conduct
This study will be performed in a professional dental clinic in Tehran city center and one of private offices in Tehran. Before treatment, a primary PA radiography of second premolar of both sides will provided, then braces will applied to all teeth (experimental second premolar) except second premolar in one side of mandible (control) which will be selected randomized. After 9 months, the second PA radiography of second premolar of both sides will be provided. Then the brace will applied to second premolar in opposite side (control). In this time, experimental and control teeth are bonded and are under orthodontic movement. The duration of this split mouth study is 9 months. Patients and researchers was blind and this study is double blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria consists of existence of second premolars in both sides of mandible, indicated for fixed orthodontics and malocclusion Class I, anterior crowding and posterior mild crowding, no dental caries and crown or root anomalies before treatment. Exclusion criteria consists of dilaceration of dental roots other dental developmental anomalies.

Intervention groups
The intervention will performed by applying orthodontic force by the Roth Bracket system with a 0.22 slot is performed on one of the second premolars. The other second premolar is a control tooth that is not under orthodontic movement.

Main outcome variables
root resorption or apposition

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170928036471N1**
Registration date: **2017-12-13, 1396/09/22**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-19, 1396/10/29**
Update count: **1**

Registration date
2017-12-13, 1396/09/22

Registrant information

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Kazem Dalaie

Name of organization / entity
Orthodontics Department of Dental school of Shahid Beheshti Medical Sciences

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Recruitment status
Recruitment complete

Funding source
Dentofacial Deformities Research Center, Research Institute of Dental Sciences, Dental School, Shahid Beheshti University of Medical Sciences

Expected recruitment start date
2017-12-01, 1396/09/10

Expected recruitment end date
2018-03-01, 1396/12/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Root length evaluation after orthodontic treatment in immature teeth

Public title
Root length evaluation after orthodontic treatment in immature teeth
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Existence of immature second mandibular premolar in both sides of mandible Indication of fixed orthodontic treatment Class I malocclusion mild crowding in posterior region of mandible
Exclusion criteria:
Dilaceration of roots other dental developmental anomalies dental caries in premolars Absence of dental crown anomalies Absence of dental root anomalies moderate or severe crowding in posterior region of mandible
Age
From **10 years** old to **15 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **32**
More than 1 sample in each individual
Number of samples in each individual: **2**
Second premolar teeth in both sides of mandible that one side act as case group and other side act as control group by random.
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: simple randomization
Randomization tool: randomization table random allocation to second premolars in right and left side of mandible for determination of case or control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients don't know that second premolar of which side of mandible get braces. The researcher and the person who measure the root length changes don't know that second premolar of which side of mandible was under orthodontic force because the periapical radiography of second premolars before treatment has no evidence of braces and also after 8 months before taking radiography of second premolars, the control tooth get brace. So nether in first periapical radiography not in second one, it is not clear that which second premolar was under force. In other hand it is not clear which tooth is in case group or control group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Dentofacial Deformities Research Center, Research Insitute of Dental dciences of
Street address
Dental School, Shahid Beheshti University of Medical Sciences, Evin, Daneshjoo Blv, Tehran
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Tehran
Postal code
1985717443
Approval date
2015-02-16, 1393/11/27
Ethics committee reference number
IR.SBMU.RIOS.REC.1396.457

Health conditions studied

1

Description of health condition studied
Orthodontic care and follow up
ICD-10 code
z46.4
ICD-10 code description
Fitting and adjustment of orthodontic device

Primary outcomes

1

Description
Dental root length
Timepoint
before intervention, 9 months after intervention
Method of measurement
by using photoshop software and evalute the digital periapical radiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention 1:apply orthodontic force on second premolar of one side of mandible by a Roth bracket system with a 0.22 slot from American Orthodontics productions, for 9 months.
Category
Treatment - Other

2

Description
Intervention 1:Routine care
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini professional Dental Clinic
Full name of responsible person
Kazem Dalaie
Street address
No26, Firuz Dehqan Street, North Felestine Ave, Keshavarz Blv, Tehran, Tehran Province
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2

Recruitment center
Name of recruitment center
Dental Office of Dr.Kazem dalaie
Full name of responsible person
Kazem Dalaie
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2nd Floor, No 3, Mirdamad Ave, Shariati Street, Davoodiyeh Quarter, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
مرکز تحقیقات ناهنجاری های دندانی فکی دندان پزشکی شهید بهشتی تهران
Full name of responsible person
Mohammadreza Badiee
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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
مرکز تحقیقات ناهنجاری های دندانی فکی دندان پزشکی شهید بهشتی تهران
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
Research Insitute of Dental Sciences, Dental School, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Reza Badiee
Position
Assistant Professor
Latest degree

Specialist
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Person responsible for updating data

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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