

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 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

Name

Kazem Dalaie

Name of organization / entity

Orthodontics Department of Dental school of Shahid Beheshti Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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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 Institute of Dental Sciences of

Street address

Dental School, Shahid Beheshti University of Medical Sciences, Evin, Daneshjoo Blv, Tehran

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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 evaluate 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 دندان فکی دندان پزشکی شهید بهشتی تهران

Full name of responsible person

Mohammadreza Badiie

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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 دندان 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 Institute of Dental Sciences, Dental School, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Reza Badiie

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

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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