

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Partial pulpotomy on caries free human teeth using iRootBP and White ProRoot MTA: a randomized controlled trial

Protocol summary

Summary

Objectives: The aim of this study is to compare the human pulp response to partial pulpotomy using White ProRoot MTA or iRoot BP in the terms of dentinal bridge formation and inflammation. **Design:** This will be a randomized single blind clinical trial. **Setting and conduct:** Thirty caries free premolar teeth from fifteen patients assigned for orthodontic extraction will be included. **Participants including major eligibility criteria:** Their parents need to sign an informed form, Patients shouldn't have any systematic complication, The teeth should be free of any symptom, caries and decalcification and should reveal a normal response to pulp sensitivity tests, No mobility or swelling in the surrounding soft tissues, sensitivity on palpation or percussion should be present. **Intervention:** A class one cavity will be prepared and the depth will be increased until the pulp exposure occurs. One millimeter of the coronal pulp will be removed. Then the exposure site will be covered using two pulpotomy agents: White ProRoot MTA as control group and iRoot BP. After six weeks (42 days) the teeth will be extracted after radiographic and clinical examination to find any sign of swelling, abscess or sinus tract. **Main outcome measures (variables):** The teeth will be sectioned and examined to compare the presence of dentinal bridge, its thickness and feature in the terms of tunnel defect formation. The underlying pulp will be assessed and graded according to the degree of inflammation as follows: grade 0 no inflammation, grade 1 mild inflammation, grade 2 moderate inflammations, grade 3 severe inflammation, grade 4 abscess formation or necrosis. Our criteria are based on ISO 7405.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102145804N2**

Registration date: **2011-08-12, 1390/05/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-12, 1390/05/21

Registrant information

Name

Mahta Fazlyab

Name of organization / entity

Islamic Azad University, Dental Branch, Tehran

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Dr. Arash Azizi, Vice chancellor for research, Islamic Azad University, Dental Branch, Tehran

Expected recruitment start date

2011-06-20, 1390/03/30

Expected recruitment end date

2012-02-28, 1390/12/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Partial pulpotomy on caries free human teeth using iRootBP and White ProRoot MTA: a randomized controlled trial

Public title

Partial pulpotomy on caries free human teeth using iRootBP and White ProRoot MTA: a randomized controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who are assigned to extract two premolar teeth in one jaw for orthodontic treatment plan will be included; Their parents need to read and sign a fully informed form; They shouldn't have any systematic complication or take any medicine during the period of study; The teeth need to be free of any symptom, caries and decalcification; They should give a normal response to pulp sensitivity tests (cold test) compared to the control tooth on the same quadrant; The teeth need to be free of mobility or swelling in the surrounding soft tissues and any sensitivity on palpation or percussion; On radiographic examination no apical lucency or PDL widening should be detected. Exclusion criteria: Any sign of crack; filling; caries or hypocalcification on teeth will cause exclusion. Also the teeth showing apical lucency or PDL widening will be excluded; Any sensitivity to cold, heat or bite will lead to exclusion; The responses beyond the normal limits to pulp vitality testing and any medicine consumption would cause exclusion.

Age

From **10 years** old to **14 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **24**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethic committee of Islamic Azad University, Dental Branch, Tehran

Street address

No 4, 10th neyestan, Pasdaran street, Tehran, Iran

City

Tehran

Postal code

1946853314

Approval date

2011-06-16, 1390/03/26

Ethics committee reference number

پ/439/د

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

pulp inflammation

ICD-10 code

K04.1

ICD-10 code description

Necrosis of pulp

Primary outcomes**1****Description**

dentinal bridge formation

Timepoint

six weeks after intervention

Method of measurement

microscopic evaluation

2**Description**

appearance of the dentinal bridge compared to normal dentin

Timepoint

six weeks after intervention

Method of measurement

microscopic evaluation of appearance of the dentinal bridge compared to normal dentin

3**Description**

thickness of the dentinal bridge compared to normal dentin

Timepoint

six weeks after intervention

Method of measurement

microscopic evaluation of thickness of the dentinal bridge compared to normal dentin

Secondary outcomes**1****Description**

inflammatory status of the pulp

Timepoint

six weeks after intervention

Method of measurement

microscopic evaluation : inflammatory cell count and their distribution

Intervention groups

1

Description

Intervention group: Partial pulpotomy using iRoot BP. Partial pulpotomy includes removal of 1mm of coronal pulp and covering the remaining tissue with a suitable material. Bioaggregate is the first nano particle, water based root end filling material. This product includes calcium silicate, calcium hydroxide, hydroxy apatite and Tanthaliium oxide. Compared to MTA, this material lacks Bismuth oxide and calcium aluminate. iRoot BP is the injectable for of Bioaggregate (Injectable Root Bioaggregate Paste).

Category

Treatment - Drugs

2

Description

control group: partial pulpotomy using White ProRoot MTA. Partial pulpotomy includes removal of 1mm of coronal pulp and covering the remaining tissue with a suitable material.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University, Dental Branch, Tehran, Endodontic department

Full name of responsible person

Mahta Fazlyab

Street address

number 4, 10th Neyestan, Pasdaran st

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Islamic Azad University, Dental Branch, Tehran

Full name of responsible person

Dr. Arash Azizi

Street address

number 4, 10th Neyestan, Pasdaran st

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Islamic Azad University, Dental Branch, Tehran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University, Dental Branch, Tehran

Full name of responsible person

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Position

post graduate student of endodontic department

Other areas of specialty/work

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Phone**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty