

# 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

+98 21 2256 4571

###### Email address

mfazlyab@dentiau.ac.ir

##### 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 Tanthanium 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

##### City

Tehran

## 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

Mahta Fazlyab

##### Position

post graduate student of endodontic department

##### Other areas of specialty/work

##### Street address

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##### Email

Dr.mfazlyab@gmail.com

##### Web page address

## Person responsible for scientific inquiries

#### Contact

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**City**

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**Postal code**

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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*