

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Clinical, radiological and histological evaluation of Pro root-MTA and Retro root-MTA in partial pulpotomy of human dental healthy pulp

Protocol summary

Summary

The main purpose during this study is evaluation of Pro root-MTA and Retro root-MTA in partial pulpotomy of human dental healthy pulp. 26 intact maxillary and mandibular third molars will be used. The teeth will be divided into 2 experimental groups (13 in every group). Before cavity preparation, teeth will be disinfected with 0.2% chlorhexidine solution. After local anesthesia and rubber dam application, occlusal Class I cavities will prepare. Bleeding will be controlled with saline irrigation, and a sterile cotton pellet is placed onto the pulp exposure sites. The teeth will be provisionally restored with glass ionomer cement. Patients in all groups will return back for clinical and radiological examinations and extraction after 2 months. Inclusion criteria are: age(18-32 years); erupted third molar; closed apex; caries free; normal sign to vitality tests and exclusion criteria are: external or internal resorption and peri apical lesion. Retro root-MTA is the intervention group and Pro root-MTA is control group. The main outcome measure is pulp health and dentin barrier formation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020420004N3**

Registration date: **2016-02-23, 1394/12/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-23, 1394/12/04

Registrant information

Name

Hengameh Bakhtiar

Name of organization / entity

Islamic Azad University of Tehran, faculty of dentistry

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2015-12-01, 1394/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical, radiological and histological evaluation of Pro root-MTA and Retro root-MTA in partial pulpotomy of human dental healthy pulp

Public title

Evaluation of Pro root-MTA and Retro root-MTA in partial pulpotomy of human dental healthy pulp

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: age between 18-32 years old; erupted third molar; closed apex; caries free; normal sign to vitality tests. Exclusion criteria: external or internal resorption; peri apical lesion.

Age

From **18 years** old to **32 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 26

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**

Moral Committee of Islamic Azad Dental university of Tehran

Street address

Azad Dental School, #10 Neyestan , Pasdaran Ave, Tehran, Iran

City

Tehran

Postal code**Approval date**

2015-06-14, 1394/03/24

Ethics committee reference number

0821.P.166.5

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

Vital pulp therapy

ICD-10 code

IA49.1

ICD-10 code description

Infection disease

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

Pulp health(Post Operative sensitivity and pain)

Timepoint

After treatment, 1 week later and before extraction

Method of measurement

Vitality test, Cold test and EPT

2**Description**

Signs of periapical pathology

Timepoint

Radiographs are taken before intervention and extraction

Method of measurement

PA Radiography

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

Dentin barrier formation

Timepoint

Eight weeks after beginning treatment

Method of measurement

Histological examination after extraction

Intervention groups**1****Description**

Before the operative protocol, each tooth will be radiologically examined to exclude the presence of caries or periapical pathology. A standardized operative procedure is followed in both experimental groups. Thermal testing (K€altespray; M&W Dental GmbH, B€udingen, Germany) will perform to assess pulp vitality. Before cavity preparation, teeth will mechanically be cleaned and disinfected with 0.2% chlorhexidine solution. After local anesthesia (Iran-Darou pakhsh) and rubber dam application, occlusal Class I cavities will prepare by using round sterile diamond burs at high speed under air-distillated water spray coolant. An exposure of approximately 1.2 mm in diameter will be made with round carbide burs (4 1.2 mm) under sterile saline cooling. New burs will be used during each operation. Bleeding will be controlled with saline irrigation, and a sterile cotton pellet is placed onto the pulp exposure sites. In group 1 the pulps and the surrounding dentins will be capped with Retro-MTA as an interventive group. Retro-MTA is a hydraulic bioceramic material for repair and vital pulp therapy. Retro-MTA is powder consisting of fine, hydrophilic particles that set in the presence of water and form a strong impermeable barrier. It contains hydraulic calcium zirconia complex as a contrast media. setting time is 150 seconds. It has no discoloration even in the blood contamination. It has no toxicity to cells in 48 hours. This means it is an ideal substance for vital pulp therapy. fast setting, no discoloration, no heavy metal, no cell toxicity, good handling properties and economic price are some of suitable properties of Retro-MTA. In vivo condition Ph is up to 12/5 and down to 7.8-8 in 4 weeks. Ex vivo study shows it has the high potential for biomineralization. هى

0/3 gram Retro root-MTA powder with 3 drops of water will be mixed by a plastic spatula for 20 seconds until the shiny surface disappears. The teeth will be provisionally restored with glass ionomer cement (Ketac Molar; 3M ESPE, Seefeld, Germany). 2 months later, patients will return back and after clinical and radiographical examinations, the teeth will be extracted and sent to a talented pathologist for histological examinations. All the clinical procedures will be performed by one experienced operator (A.N.) in the Endodontic Department of Islamic Azad Dental university of Tehran.

Category

Treatment - Other

2

Description

Before the operative protocol, each tooth will be radiologically examined to exclude the presence of caries or periapical pathology. A standardized operative procedure is followed in both experimental groups. Thermal testing (K€altespray; M&W Dental GmbH, B€udingen, Germany) will perform to assess pulp vitality. Before cavity preparation, teeth will mechanically be cleaned and disinfected with 0.2% chlorhexidine solution. After local anesthesia (Iran-Darou pakhsh) and rubber dam application, occlusal Class I cavities will prepare by using round sterile diamond burs at high speed under air-distillated water spray coolant. An exposure of approximately 1.2 mm in diameter will be made with round carbide burs (4 1.2 mm) under sterile saline cooling. New burs will be used during each operation. Bleeding will be controlled with saline irrigation, and a sterile cotton pellet is placed onto the pulp exposure sites ProRoot MTA (Dentsply-USA) is a water-based material which uses for apexification, repairing root perforations and As a pulp capping material. It sets in the presence of moisture. The main constituent phases are tricalcium and dicalcium silicate and tricalcium aluminate. In group II exposed pulps and the surrounding dentins will be capped with Retro-MTA. 0/3 gram Retro root-MTA powder with 3 drops of water will be mixed by a plastic spatula for 20 seconds until the shiny surface disappears. 2 months later, patients will return back and after clinical and radiographical examinations, the teeth will be extracted and sent to a talented pathologist for histological examinations. All procedures will be performed by one experienced operator (A.N.) in the Endodontic Department of Dental School.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad dental university

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice challenger of research, Islamic Azad Dental University of Tehran

Full name of responsible person

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Street address

Dental school, #10 Neyestan, Pasdaran Ave, Tehran, Iran

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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

Vice challenger of research, Islamic Azad Dental University of 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 Dental university

Full name of responsible person

Hengameh Bakhtiar

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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