

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### Comparison of the outcome of pulpotomy on permanent mature molars with carious pulp exposure with conventional root canal therapy: A comparative randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of the outcome of pulpotomy on permanent mature molars with carious pulp exposure with conventional root canal therapy

##### Design

This multi-center randomized controlled clinical trial (phase 3) aims on a total of 900 volunteers from the population of patients with irreversible pulpitis of molar teeth, referring to the post graduate endodontic departments of participating universities. Volunteers who meet the inclusion criteria are randomly (computer randomization) assigned into 3 mentioned study groups (each group consists of 300 patients).

##### Settings and conduct

Location of study : Endodontic department of Shahid Beheshti, Tabriz, Shahed, Azad, Khorasgan, Yazd, Kerman, Zahedan, Shiraz universities of medical sciences.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria : A vital molar tooth A history of pain indicating irreversible pulpitis Patients in the range of 12 to 65 years Patients who accept to be and will be available for recalls Patients who approve and sign the written informed consent Exclusion Criteria : Patients with systemic conditions that disturb tissue healing process. Pregnant/nursing women Physically disabled or mentally retarded patients Teeth require complicated build-ups, crown lengthening or prosthetic crown. Teeth with localized periodontal disease (i.e. probing depth more than 3 mm) Internal/external root resorption or pulp calcification Teeth with history of trauma or Swelling of surrounding soft tissues Teeth with immature apices or with Presence of sinus tract

##### Intervention groups

1- Root Canal Therapy and coronal restoration 2- Pulpotomy with CEM Cement and coronal restoration 3- Pulpotomy with ProRoot MTA and coronal restoration

##### Main outcome variables

Clinical and radiographic signs/symptoms at 6, 12 and 24 months post-treatment.

#### General information

##### Reason for update

##### Acronym

Root canal therapy and pulpotomy

##### IRCT registration information

IRCT registration number: **IRCT20151226025695N3**

Registration date: **2019-02-06, 1397/11/17**

Registration timing: **retrospective**

Last update: **2019-02-06, 1397/11/17**

Update count: **0**

##### Registration date

2019-02-06, 1397/11/17

##### Registrant information

##### Name

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##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research, Ministry of Health and Medical Education, Islamic Republic of Iran, Shahid Beheshti University of Medical Sciences, Research Institute of Dental Sciences, Iranian Center for

**Expected recruitment start date**

2017-03-05, 1395/12/15

**Expected recruitment end date**

2018-03-06, 1396/12/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the outcome of pulpotomy on permanent mature molars with carious pulp exposure with conventional root canal therapy: A comparative randomized clinical trial

**Public title**

Outcome of root canal therapy and pulpotomy on permanent mature molars

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

A vital molar tooth (confirmed with cold spray and electric pulp tester before treatment and visual inspection of pulpal hemorrhage after access cavity preparation) A history of pain indicating irreversible pulpitis (i.e. spontaneous localized/generalized pain, pain stimulated by hot and cold fluids that lasts after elimination of the stimulus and is reproducible with cold testing) Pulp exposure during caries removal when no sign of irreversible pulpitis is present Patients in the range of 12 to 65 years Patients who accept to attend for recalls Patients who approve and sign the written informed consent

**Exclusion criteria:**

Patients with systemic conditions that disturb tissue healing process (including diabetes, cancer, endocrine diseases, AIDS and consumption of corticosteroids) Patients with epinephrine intolerance Pregnant/nursing women Physically disabled or mentally retarded patients Patients with poor oral hygiene or those with periodontal diseases, where the long term preservation of the tooth may not be possible Immigrants such as those from Afghanistan, who are likely to leave the country during the subsequent two years Patients younger than 12 (for 1st molar treatment) and 17 (for 2nd molar treatment) and patients older than 65; Non-vital/partially necrotic teeth confirmed with primary examinations or diagnosed after access cavity preparation Teeth with pulpal inflammation spreading beyond the canal orifices, and continuous bleeding after placement of cotton pellet soaked in 2.5% sodium hypochlorite for a maximum of 10 minutes Teeth that are not appropriate candidates for class I and II (Occlusal, MO, DO, MOD) restoration and require complicated build-ups, crown lengthening or prosthetic crown Teeth with localized periodontal disease (i.e. probing depth more than 3 mm) where the tooth survival is not endangered but pulpal irritation and disturbed healing due to root exposure is likely

Internal/external root resorption or pulp calcification detectable in periapical radiography Teeth with history of trauma Swelling of surrounding soft tissues Teeth with immature apices Presence of sinus tract

**Age**

From **12 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **900**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, a software has been designed to randomize the treatment group of participating patients. For each practitioner, eligible patients will be randomized into three study arms, using a computer-generated system; Randomization performed online via www.mcrct.ir website right after the recording of patient's demographic data and before the starting of treatment (allocation concealment). Patients stratified with 1:1:1 allocation in the three study arms.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description**

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee, Research Institute of Dental Sciences, Iranian Center for Endodontic Research, Sha

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Research Institute of Dental Sciences, Shahid Beheshti Dental School, Evin

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**Approval date**

2017-01-12, 1395/10/23

**Ethics committee reference number**

IR.SBMU.RIDS.REC.1395.320

## Health conditions studied

### 1

#### Description of health condition studied

Diseases of pulp and periapical tissues

#### ICD-10 code

K04

#### ICD-10 code description

Diseases of pulp and periapical tissues

### 2

#### Description of health condition studied

Inflammation of the pulp

#### ICD-10 code

K04.0

#### ICD-10 code description

Pulpitis

### 3

#### Description of health condition studied

Necrosis of pulp

#### ICD-10 code

K04.1

#### ICD-10 code description

Necrosis of pulp

### 4

#### Description of health condition studied

Pulp degeneration

#### ICD-10 code

K04.2

#### ICD-10 code description

Pulp degeneration

### 5

#### Description of health condition studied

Acute apical periodontitis of pulpal origin

#### ICD-10 code

K04.4

#### ICD-10 code description

Acute apical periodontitis of pulpal origin

### 6

#### Description of health condition studied

Chronic apical periodontitis

#### ICD-10 code

K04.5

#### ICD-10 code description

Chronic apical periodontitis

### 7

#### Description of health condition studied

Periapical abscess with sinus

#### ICD-10 code

K04.6

#### ICD-10 code description

Periapical abscess with sinus

### 8

#### Description of health condition studied

Periapical abscess without sinus

#### ICD-10 code

K04.7

#### ICD-10 code description

Periapical abscess without sinus

## Primary outcomes

### 1

#### Description

Sign and symptoms of pulpal inflammation/infection (spontaneous unstimulated pain)

#### Timepoint

One week and 6, 12 and 24 months after intervention

#### Method of measurement

Clinical examination and VAS (visual analogue scale) questionnaire

### 2

#### Description

Sign and symptoms of pulpal inflammation (internal/external resorption)

#### Timepoint

One week and 6, 12 and 24 months after intervention

#### Method of measurement

Periapical radiographs

### 3

#### Description

Sign and symptoms of periapical inflammation (pain on percussion and palpation)

#### Timepoint

One week and 6, 12 and 24 months after intervention

#### Method of measurement

Clinical examination and VAS (visual analogue scale) questionnaire

### 4

#### Description

Sign and symptoms of periapical infection (pain, redness, swelling or formation of sinus tract)

#### Timepoint

One week and 6, 12 and 24 months after intervention

#### Method of measurement

Clinical examination and VAS (visual analogue scale) questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**

Intervention group 1: Pulpotomy with CEM Cement

**Category**

Prevention

**2**

**Description**

Intervention group 2: Pulpotomy with ProRoot MTA

**Category**

Prevention

**3**

**Description**

Control group: Root canal therapy

**Category**

Prevention

**Recruitment centers**

**1**

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## Sponsors / Funding sources

### 1

#### Sponsor

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#### Grant name

#### Grant code / Reference number

IR.SBMU.RIDS.REC.1395.320

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

Yes

#### Title of funding source

Vice Chancellor for Research, Ministry of Health and  
Medical Education, Islamic Republic of Iran

**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**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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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