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

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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

Endodontic Research

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 disturbe 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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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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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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Assistant Professor

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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