

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of full pulpotomy in cariously exposed mature permanent molar teeth with new calcium silicate cement : A 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 controlled clinical trial aims on a total of 90 volunteers from the population of patients with irreversible pulpitis of molar teeth, referring to the post graduate endodontic departments of dental faculty of Zahedan. Volunteers who meet the inclusion criteria are randomly (computer randomization) assigned into 3 mentioned study groups (each group consists of 30 patients) .

Settings and conduct

Location of study : Endodontic department of Zahedan university 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 50 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 tracts.

Intervention groups

1- Root Canal Therapy and coronal restoration 2- Pulpotomy with new calcium silicate Cement and coronal restoration 3- Pulpotomy with MTA and coronal restoration

Main outcome variables

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

General information

Reason for update

Acronym

Root canal therapy and pulpotomy

IRCT registration information

IRCT registration number: **IRCT20220305054200N1**

Registration date: **2022-04-25, 1401/02/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-25, 1401/02/05**

Update count: **0**

Registration date

2022-04-25, 1401/02/05

Registrant information

Name

Farnaz Faramarzian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 1814

Email address

farnazfaramarzian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-24, 1401/02/04

Expected recruitment end date

2022-10-21, 1401/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of full pulpotomy in cariously exposed mature permanent molar teeth with new calcium silicate cement : A 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 50 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 15 (for 2nd molar treatment) and patients older than 50 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

AgeFrom **12 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **90****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 right after the recording of patient's demographic data and before the starting of treatment. 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 of Zahedan University of Medical Sciences

Street address

Dental Faculty Of Zahedan, Azadegan Sharghi Ave.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9817699693

Approval date

2022-02-26, 1400/12/07

Ethics committee reference number

IR.ZAUMS.REC.1400.412

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

Pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

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

Timepoint

Six months after treatmentOne week and 6 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

Six months after treatmentOne week and 6 months after intervention

Method of measurement

Periapical radiographs

3

Description

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

Timepoint

Six months after treatmentOne week and 6 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

Six months after treatmentOne week and 6 months after intervention

Method of measurement

Clinical examination and VAS (visual analogue scale) questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Root canal therapy

Category

Prevention

2

Description

Intervention group 1: Pulpotomy with new calcium silicate cement

Category

Prevention

3

Description

Intervention group 2: Pulpotomy with MTA

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental faculty of Zahedan

Full name of responsible person

Farnaz Faramarzian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Somaye Ansari Moghadam

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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

Zahedan University of Medical Sciences

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

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Farnaz Faramarzian

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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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