

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of pulpotomized primary molar teeth using Calcium-Enriched Mixture and Ferric sulfate clinically and radiographically in children: a randomized clinical trial

#### Protocol summary

##### Study aim

Comparison of clinical and radiographic success rate and pain after pulpotomy in primary molars using Calcium-Enriched Mixture (CEM) cement and Ferric sulfate

##### Design

Clinical trial with intervention groups, with parallel, two-way blind and randomized groups on 24 patients. Simple randomization method (flip the coin) will be used to randomize.

##### Settings and conduct

This project will be carried out in the Department of Pediatrics of the Kerman Dentistry School. Before treatment, the patient becomes aware completely of two types of material used for treatment, but he/she does not know which substance is used for her/his tooth during treatment. Follow up evaluations are carried out by two researchers who are not aware of the type of treatment and they will comment on radiographic criteria. The statistician is not aware of the type of treatment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: pulp exposure due to caries; restorable teeth with stainless steel crown; hemostasis could be easily achievable. Non inclusion criteria: pathologic mobility; history of spontaneous pain; sinus tracts; abscess or swelling; internal or pathologic external root resorption; interradicular or periapical radiolucency.

##### Intervention groups

Intervention group 1: CEM cement. This material is combined according to the manufacturer's instructions and placed on the pulp. Intervention group 2: Ferric sulfate. 15.5% ferric sulfate is placed on the pulp for 15 seconds. It is then washed and zonalin base is placed in the pulp chamber.

##### Main outcome variables

Internal resorption; dental abscess and fistula

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171020036896N8**

Registration date: **2020-06-26, 1399/04/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-26, 1399/04/06**

Update count: **0**

##### Registration date

2020-06-26, 1399/04/06

##### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 32119023

##### Email address

sajadi@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-09, 1399/02/20

##### Expected recruitment end date

2020-07-10, 1399/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of pulpotomized primary molar teeth using Calcium-Enriched Mixture and Ferric sulfate clinically and radiographically in children: a randomized clinical trial

## Public title

Clinical and radiographic success and pain after pulpotomy treatment using Calcium-Enriched Mixture and Ferric sulfate

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Pulp exposure due to caries Restorable teeth with stainless steel crown Hemostasis could be easily achievable

### Exclusion criteria:

Pathologic mobility History of spontaneous pain Sinus tracts , abscess or swelling Internal or pathologic external root resorption Interradicular or periapical radiolucency

## Age

From **3 years** old to **9 years** old

## Gender

Both

## Phase

1-2

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, the simple randomization method (flip the coin) will be used. In such a way that one of the study groups will be considered as heads and the other group will be considered as tails. Then the same number of coins will be thrown based on the sample size. Finally, to prevent disclosure of random sequencing, the allocation concealment will be used.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Before treatment, the patient becomes aware completely of two types of material used for treatment, but he/she does not know which substance is used for her/his tooth during treatment. Follow up evaluations are carried out by two researchers who are not aware of the type of treatment and they will comment on radiographic criteria. The statistician is not aware of the type of treatment.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kerman University of Medical Sciences

##### Street address

Shafa avenue

##### City

Kerman

##### Province

Kerman

##### Postal code

7618759689

#### Approval date

2014-12-06, 1393/09/15

#### Ethics committee reference number

IR.KMU.REC.1393.538

## Health conditions studied

### 1

#### Description of health condition studied

Pulpitis

#### ICD-10 code

Pulpitis

#### ICD-10 code description

Pulpitis

## Primary outcomes

### 1

#### Description

Internal resorption

#### Timepoint

6 months after the start of intervention

#### Method of measurement

Through radiographic examination

### 2

#### Description

Dental abscess and fistula

#### Timepoint

6 months after the start of intervention

#### Method of measurement

Through clinical examination

## Secondary outcomes

### 1

#### Description

External resorption

**Timepoint**

6 months after the start of the intervention

**Method of measurement**

Through radiographic examination

**2****Description**

Furcation radiolucency

**Timepoint**

6 months after the start of the intervention

**Method of measurement**

Through radiographic examination

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

Intervention group 1: After pulpotomy, the CEM cement was prepared according to the manufacturer's instructions and placed in the pulp chamber.

**Category**

Treatment - Drugs

**2****Description**

Intervention group 2: a cotton ball impregnated by ferric sulfate 15.5% was placed on the orifices of canals for 15 seconds.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Faculty of Dentistry

**Full name of responsible person**

Farzaneh Jalalih

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Shafa Ave

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Kerman

**Province**

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**Postal code**

7618759689

**Phone**

+98 34 3211 8074

**Email**

fznjalali@gmail.com

**Sponsors / Funding sources****1****Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Abbas Pardakhti

**Street address**

Shafa avenue

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Kerman

**Province**

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

**Title of funding source**

Kerman 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Farzaneh Jalali

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Farzaneh Jalali

**Position**

resident

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Kerman University of Medical Sciences

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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