# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

30 May 2026

## A comparison of post operative pain following Mineral trioxide aggregate and Calcium enriched material pulpotomy in primary molars

## Protocol summary

**Summary**

Aim: This randomized clinical trial –split mouth study investigated post-operative pain following use of mineral trioxide aggregate (MTA) and calcium enriched mixture (CEM) cement as pulp dressing biomaterials in vital pulpotomy of carious primary molars. Materials and Methods: Forty-five children, aged 6-10 years, were included in this study. Each child had two cariously involved primary molar teeth in need of pulpotomy. Following caries removal and preparing access cavity in one of their carious teeth, either MTA or CEM were randomly used as pulpotomy agents, while their other carious primary molar teeth were capped with the other material. Then the teeth were permanently restored with stainless steel crown. Post-operative pain was recorded by child and the parents by using Wong-Baker faces pain rating scale during one week after operation.

## General information

**Acronym**

CEM/MTA

**IRCT registration information**

IRCT registration number: **IRCT2013091914712N1**
Registration date: **2014-11-17, 1393/08/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2014-11-17, 1393/08/26

**Registrant information**

**Name**

Hamideh Barghi

**Name of organization / entity**

Kerman University for Medical Sciences, Dental School.

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Oral and Dental Diseases Research Center, Kerman University of Medical Sciences

**Expected recruitment start date**

2013-03-03, 1391/12/13

**Expected recruitment end date**

2013-11-20, 1392/08/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A comparison of post operative pain following Mineral trioxide aggregate and Calcium enriched material pulpotomy in primary molars

**Public title**

The effect of pulp dressing agents on post operative pain in children.

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: primary molar with out sign and symptom; same caries;no sensitivity to percussion; there is no pain except pain after eating; no clinical and radiographic evidence of pulp degeneration; Less than two-thirds of the root is involved; diseases that are not prescribed pulp therapy (leucemia). Exclusion criteria: PA radiograph of a tooth is made and if there are any

findings of internal analysis; thickening of the PDL; radiolucency; and calcified degeneration

**Age**
From **6 years** old to **12 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **45**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Single

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Oral and Dental Research Center

**Street address**
Kawthar blvd, Kerman

**City**
Kerman

**Postal code**

**Approval date**
2012-06-20, 1391/03/31

**Ethics committee reference number**
k/91/267

## Health conditions studied

### 1

**Description of health condition studied**
reversible pulpitis

**ICD-10 code**
K04.0

**ICD-10 code description**
pulpitis

## Primary outcomes

### 1

**Description**
Pain

**Timepoint**
1-7 days after treatment

**Method of measurement**
Wong-Baker faces pain rating scale.

## Secondary outcomes

### 1

**Description**
post operative pain

**Timepoint**
from 1st to 7th day after treatment

**Method of measurement**
visual analogue scale (VAS)

## Intervention groups

### 1

**Description**
interventiom group: use of CEM with standard pulpotomy method (2mm thickness)

**Category**
Other

### 2

**Description**
I nterventiom group: use of MTA with standard pulpotomy method (2mm thickness)

**Category**
Other

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**
Kerman Univesity of Medical Sciences -School of Dentistry

**Full name of responsible person**
Hamideh Barghi,resident of pediatric dentistry

**Street address**
Pediatric Dentistry Department, School of Dentistry, Shafa Street, Jomhori Islami Blvd, Kerman, Iran

**City**
Kerman

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**
Kerman University of Medical Sciences

**Full name of responsible person**
miss Hassani

**Street address**

Tahmasb abad cross, Kerman, Iran

**City**

Kerman

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Kerman University of Medical Sciences

**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**

Kerman University of Medical Sciences-School of Dentistry.

**Full name of responsible person**

Hamideh Barghi

**Position**

Resident of pediatric dentistry

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Full Proffessor Endodontist

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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*