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.

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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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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