Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of clinical and radiographic success of primary molars direct pulp capping using Mineral Aggregate Trioxide and Calcium Enriched Mixture

Protocol summary

Summary

Aim: to compare clinical and radiographic success rates of direct pulp capping (DPC) in primary molars teeth using Mineral Aggregate trioxide(MTA) and Calcium Enriched Mixture(CEM) cement as a novel endodontic biomaterial. Materials and methods: This triple blind randomized controlled clinical trial carried on 21 children 5-8 years old that had at least 2 deep decayed primary molars teeth and the teeth had no spontaneous pain, swelling , fistula, sinus tract, sensitivity to percussion and palpation. The patient did not have systemic diseases. Every tooth, after local anesthesia, was isolated with cotton roll and caries was removed. The bleeding of pin point exposure was controlled and one of two materials was randomly applied on the pin point, then the tooth restored with amalgam. The patients were recalled every 6 and 12 months to evaluate clinical and radiographic success.

General information

Acronym

DPC

IRCT registration information

IRCT registration number: **IRCT138802161882N1**
Registration date: **2010-05-27, 1389/03/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2010-05-27, 1389/03/06

Registrant information

Name

Masoud Fallahinejad Ghajari

Name of organization / entity

Facualty of Dentistry, Shahid Beheshti University Of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Iranian Center for Endodontics Research, Shahid Beheshti University of Medical Siences

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2009-09-06, 1388/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of clinical and radiographic success of primary molars direct pulp capping using Mineral Aggregate Trioxide and Calcium Enriched Mixture

Public title

Pulp Treatment of primary teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: at least 2 decayed primary molars, no spontaneous pain, no sensitivity to percussion/palpation, no pathologic mobility, no swelling/fistula, no forcation lucency, no internal/external root resorption. Exclusion

criteria: Systemic diseases, use of special drugs, absence of accessor permanent toot, priodontal packet more than 3mm, sinus tract.

Age
From **5 years** old to **8 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **21**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Deputy of Shahid Beheshti University Medical Siences

Street address
Next to Taleghni Haspital, Evin

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Tehran

Postal code

Approval date
2013-09-04, 1392/06/13

Ethics committee reference number
87-01-152-5724-1060

Health conditions studied

1

Description of health condition studied
primary tooth pulp exposure

ICD-10 code
K04

ICD-10 code description
Diseases of pulp and periapical tissues

Primary outcomes

1

Description
clinical health (absence of signs and symptomes of pulp disease) of treated tooth

Timepoint
6 monts

Method of measurement
examination

2

Description
radiographic health of treated tooth

Timepoint
6 months

Method of measurement
radiography

Secondary outcomes

1

Description
Dentine Bridge Formation in exposure area

Timepoint
6 monthes

Method of measurement
Radiographic examination

Intervention groups

1

Description
pulp capping using Mineral Aggregate trioxide (MTA)

Category
Treatment - Drugs

2

Description
pulp capping using Calcium Enriched Mixture (CEM)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
School of Dentistey, Shahid Beheshti University of Medical Siences

Full name of responsible person
Dr.Masoud Fallahinegad Ghajari

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian Center for Endodontic Research
Full name of responsible person
Dr.Saeed Asgary
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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
Iranian Center for Endodontic Research
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

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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