

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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

Faculty of Dentistry, Shahid Beheshti University Of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2240 3010

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

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

##### 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

##### City

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

##### Street address

School of Dentistry, Daneshjoo Boulevd, Evin

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Iranian Center for Endodontic Research

**Full name of responsible person**

Dr.Saeed Asgary

**Street address**

School Dentistry, Daneshjoo Boulevd, Evin

**City**

Tehran

**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

### Contact

**Name of organization / entity**

School of Dentistry, Shahid Beheshti University of  
Medical Sciences

**Full name of responsible person**

Dr.Masou Fallahinejad Ghajari

**Position**

Pedodontist/Assotiated Prof.

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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Endodontist/Professor

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## Person responsible for updating data

### Contact

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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*