

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

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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
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Full name of responsible person

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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

Contact

Name of organization / entity

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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