

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of effectiveness of pulpotomy of primary molar teeth with Calcium-enriched mixture in children 4 to 7 years with irreversible pulpitis

Protocol summary

Summary

The purpose of this clinical study is to evaluate the clinical effect of calcium-enriched cement in pulpotomy of primary molars with irreversible pulpitis. The Inclusion criterion is carious lesion on vital molar teeth surfaces. The exclusion criteria are children with systemic diseases, children with extremely poor oral hygiene, teeth with external or internal root resorption, root canal calcification and non-restorable teeth. In this I study, 50 patients aged 4 to 7 years are selected through simple sampling method from Faculty of Dentistry in Shiraz. Intervention in this study is pulpotomy with Calcium enriched cement: After adequate local anesthesia, the pulpotomy procedures were performed with rubber dam or cotton plate isolation following complete removal of caries using fissure diamond burs and round stainless steel burs. . Following coronal pulp amputation, the pulp chamber was irrigated using normal saline as well as cotton pellets wetted with normal saline to homeostasis. A base of about 2 mm CEM cement (BioniqueDent, Tehran, Iran) was placed over the amputation site. A wet cotton pellet was placed over the cement and the teeth were temporarily sealed with zinc phosphate cement. Data of this intervention are collected in four stages: 1. One week after the intervention 2. Three months after the intervention 3. Six months after the intervention 4. Twelve months after the intervention. Primary outcomes include: Swelling, tenderness to percussion, pathologic mobility, redness and pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201310257402N4**

Registration date: **2013-11-21, 1392/08/30**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-11-21, 1392/08/30

Registrant information

Name

Mahtab Memarpour

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1626 3192

Email address

memarpour@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2013-08-27, 1392/06/05

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of pulpotomy of primary molar teeth with Calcium-enriched mixture in children 4 to 7 years with irreversible pulpitis

Public title

Pulpotomy of primary molar teeth with irreversible

pulpitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Carious lesion on the molar tooth surface not extending toward the root; Vital molar teeth.

Exclusion criteria: Children with systemic diseases; Children with extremely poor oral hygiene; Children with periodontal problems; Teeth with external or internal root resorption; Root canal calcification in pre-treatment radiographs; Non-restorable teeth.

Age

From **4 years** old to **7 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

Clinicaltrials.gov

Secondary trial Id

NCT01561183

Registration date

2012-03-14, 1390/12/24

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Pediatric Dentistry Department, Faculty of Dentistry,
Ghomabad, Ghasrodasht

City

Shiraz

Postal code

Approval date

2013-08-24, 1392/06/02

Ethics committee reference number

CT-P-92-5759

Health conditions studied

1

Description of health condition studied

Pulpotomy of primary molar teeth with

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Pathologic mobility

Timepoint

Seventh day

Method of measurement

Physical examination, Observation

2

Description

Pain

Timepoint

Seventh day, Three months after the intervention, Six months after the intervention, Twelve months after the intervention

Method of measurement

Physical examination, Observation

3

Description

Abscess

Timepoint

Seventh day, Three months after the intervention, Six months after the intervention, Twelve months after the intervention

Method of measurement

Physical examination, Observation

4

Description

Swelling

Timepoint

Seventh day, Three months after the intervention, Six months after the intervention, Twelve months after the intervention

Method of measurement

Physical examination, Observation

5

Description

Tenderness to percussion

Timepoint

Seventh day, Three months after the intervention, Six months after the intervention, Twelve months after the intervention

Method of measurement

Physical examination

6**Description**

Redness

Timepoint

Three months after the intervention, Six months after the intervention, Twelve months after the intervention

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups**1****Description**

pulpotomy with Calcium enriched cement: After obtaining adequate local anesthesia, the pulpotomy procedures were performed with rubber dam or cotton plate isolation following complete removal of caries using fissure diamond burs and round stainless steel burs. . Following coronal pulp amputation, the pulp chamber was irrigated using normal saline as well as cotton pellets wetted with normal saline to homeostasis. A base of about 2 mm CEM cement (BioniqueDent, Tehran, Iran) was placed over the amputation site. A wet cotton pellet was placed over the cement and the teeth were temporarily sealed with zinc phosphate cement.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shiraz Faculty of Dentistry

Full name of responsible person

Mahtab Memarpour

Street address

Pediatric Dentistry Department, Faculty of Dentistry, Ghomabad, Ghasrodasht

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Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Doctor Ali Poust Foroushfar

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz 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**

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Associate Professor of Pediatric Dentistry / Faculty

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

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City

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Postal code**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