Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 l 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
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Doctor Ali Poust Foroushfard
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
Mahtab Memarpour
Position
Associate Professor of Pediatric Dentistry / Faculty
Other areas of specialty/work
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Person responsible for scientific 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