

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparing the effects of Sodium Hypochlorite 5% and Calcium Enriched Mixture cement versus Formocresol on clinical and radiographic outcomes of pulptherapy of primary molars in children 5-8 years old_ A clinical trial

Protocol summary

Summary

In this double-blind clinical trial study, 90 healthy 5-8 year-old children with the following inclusion criteria were invited to participate in this study: 1. Children who will be able to cooperate in order to pulp therapy. 2. All primary molars should be exposed due to decay and pulp should be vital. 3. Absence of pathologic internal or external root resorption, or any evidence of inter-radicular bone destruction in a preliminary radiography. 4. There should not be any signs of pulp degeneration (spontaneous pain, fistula, mobility, swelling and sinus tract) prior to treatment. 5. All teeth should be restorable with Posterior Stainless Steel Crown. Teeth were divided to 3 groups randomly. After local anesthesia injection and isolation, caries was removed. After access cavity preparation, standard pulp therapy with Calcium Enriched Mixture cement, Sodium Hypochlorite and Formocresol was done. The formocresol group was considered as control group. A base of zinc oxide eugenol was placed in the pulp chamber of both treatment and control groups, and a stainless steel crown was cemented with polycarboxylate cement. The teeth were evaluated at 3, 6 and 12 months after treatment. A blind pedodontist examined the patients clinically and a blind radiologist interpreted the radiographs. Data were analyzed by software SPSS version 19. McNemar test was also used for comparing the frequency of success and failure of treatment groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013092414749N1**

Registration date: **2014-03-16, 1392/12/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-16, 1392/12/25

Registrant information

Name

Seyede Zeinab Salehi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2891

Email address

jabbarifar@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

not private

Expected recruitment start date

2012-11-05, 1391/08/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Sodium Hypochlorite 5% and Calcium Enriched Mixture cement versus Formocresol on clinical and radiographic outcomes of pulptherapy of primary molars in children 5-8 years old_ A clinical trial

Public title

Pulpotomy with Formocresol, Calcium Enriched Mixture cement and Sodium Hypochlorite 5%

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: 1. Children who will be able to cooperate in order to primary teeth pulp-therapy. 2. All primary molars should be exposed due to decay and pulp should be vital. 3. Absence of pathologic internal or external root resorption, or any evidence of inter-radicular bone destruction in a preliminary radiography 4. There should not be any clinical signs of pulp degeneration such as spontaneous pain, fistula, mobility, swelling and sinus tract prior to treatment. 5. All teeth should be restorable with Posterior Stainless Steel Crown. Exclusion criteria: 1. Parents who are opposed to participation in the study. 2. The children out of 5-8 age range. 3. Patients with a history of systemic disease.

Age

From 5 years old to 8 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Sampling method: Convenience sampling method was considered for selection of 90 patients referred to Isfahan Dental School. Patients number 1 to 30 were treated with CEM cement, 31 to 60 with Hypochlorite Sodium and 61 to 90 with Formocresol as control group. double blind study: 1. Blind patient about treatment method. 2. A blind pedodontist that evaluate clinical signs and a blind radiologist that evaluate radiologic signs

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Isfahan University of Medical Sciences

Street address

Dental School, Medical University of Sciences, Hezar Jerib Street, Azadi Square, Isfahan, Iran

City

Isfahan

Postal code

81746-73461

Approval date

2012-10-29, 1391/08/08

Ethics committee reference number

391363

Health conditions studied**1****Description of health condition studied**

pulpitis

ICD-10 code

K04.0

ICD-10 code description

بیماری های پالپ و بافت های اطراف اپکس

Primary outcomes**1****Description**

Mobility

Timepoint

3, 6 and 12 months after treatment

Method of measurement

By dental mirror on one side of tooth and fingers on the other side

2**Description**

Swelling

Timepoint

3, 6 and 12 months after treatment

Method of measurement

With clinical observation

3**Description**

Sinus tract and puss discharge from orifices of canals

Timepoint

3, 6 and 12 months after treatment

Method of measurement

With clinical observation

4**Description**

Internal resorption

Timepoint

3, 6 and 12 months after treatment

Method of measurement

Graphic evaluation

5

Description

Furcation lesion

Timepoint

3, 6 and 12 months after treatment

Method of measurement

Graphic evaluation

6

Description

Peri apical destruction

Timepoint

3, 6 and 12 months after treatment

Method of measurement

Graphic evaluation

7

Description

Involvement of periodontal ligament

Timepoint

3, 6 and 12 months after treatment

Method of measurement

Graphic evaluation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 1. After pulp amputation and hemostasis occurring: CEM cement paste(Bionique Dent-Iran), obtained by mixing CEM cement powder with distilled water provided in 3:1 ratio, then was placed in pulp chamber by amalgam carrier. Cement thickness should be 2 mm.

Category

Treatment - Drugs

2

Description

1. Intervention group 2. After the standard pulp-therapy, a cotton pellet soaking in 5% Hypochlorite sodium (pak daroo) was placed in chamber for 30 seconds and then pulp chamber was washed out with normal saline

Category

Treatment - Drugs

3

Description

Control group: 1. After completion of pulp therapy, the control teeth were treated with sterile cotton pellet moistened with Formocresol (Sultan) which was placed in pulp chamber for 5 minutes and then removed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Dental School

Full name of responsible person

Seyede Zeinab Salehi

Street address

Isfahan Dental School, Medical University of Sciences, Shohadaye sofe Street, Azadi Square, Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Peyman Adibi

Street address

Vice chancellor for research, Isfahan Medical University of Sciences, Shohadaye sofe Street, Azadi Square, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

391363

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Isfahan 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

Isfahan University of Medical Sciences, Dental School

Full name of responsible person

Seyed Ebrahim Jabarifar

Position

Pediatric Dentistry Specialist

Other areas of specialty/work

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Seyed Ebrahim Jabarifar

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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