Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 radiograghy. 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 polycarboxlyate 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 radiograghs. 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)

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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 radiograghy 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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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