Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparative Assessment of Clinical and Radiographic Success of Pulpotomy with Cold Ceramic and CEM Cement in Primary Second Molars: a Randomized Controlled Clinical Trial

Protocol summary

Study aim

Determining the clinical success of pulpotomy with cold ceramic in primary second molars at 6-month follow-up Determining the clinical success of pulpotomy with cold ceramic in primary second molars at 12-month follow-up Determining the clinical success of pulpotomy with CEM cement in primary second molars at 6-month follow-up Determining the clinical success of pulpotomy with CEM cement in primary second molars at 12-month follow-up Determining the radiographic success of pulpotomy with cold ceramic in primary second molars at 6-month follow-up Determining the radiographic success of pulpotomy with cold ceramic in primary second molars at 12-month follow-up Determining the radiographic success of pulpotomy with CEM cement in primary second molars at 6-month follow-up Determining the radiographic success of pulpotomy with CEM cement in primary second molars at 12-month follow-up

Design

A clinical trial with Cold Ceramic and CEM Cement groups, with crossover, double-blind, randomized, on 24 patients and 48 teeth. The envelope method was used for randomization.

Settings and conduct

The experiment will be conducted in the pediatric department of Shahid Beheshti Dental School. Isolation will be done with rubber dam. After caries removal, pulpotomy treatment will be performed on the teeth according to the assigned group. The teeth in both groups will be restored with stainless steel crowns. Clinical and radiographic results will be evaluated after 6 and 12 months. The participant and the statistician will be blinded.

Participants/Inclusion and exclusion criteria

Children aged 4-9 years with at least two deciduous second molars requiring pulpotomy in one jaw will be included in the study.

Intervention groups

In one group, pulpotomy is performed with Cold Ceramic and in the other group, pulpotomy is performed with CEM Cement.

Main outcome variables

Performing pulpotomy with higher success

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250712066460N1**
Registration date: **2025-08-04, 1404/05/13**
Registration timing: **prospective**

Last update: **2025-08-04, 1404/05/13**
Update count: **0**

Registration date

2025-08-04, 1404/05/13

Registrant information

Name

Mobina Habibollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date

2025-11-21, 1404/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Assessment of Clinical and Radiographic Success of Pulpotomy with Cold Ceramic and CEM Cement in Primary Second Molars: a Randomized Controlled Clinical Trial

Public title

Comparative Assessment of c Success of Pulpotomy with Cold Ceramic and CEM Cement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with healthy systemic conditions (ASA1) Children with at least 2 primary second molars requiring pulpotomy (in one jaw) Children with Frankel cooperation levels 3 and 4 Children or parents voluntarily agree to participate in the study and sign the consent form

Exclusion criteria:

Teeth with evidence of pulp necrosis Teeth with signs of irreversible pulpitis (hyperemic pulp) Teeth with pathological external or internal resorption Unrestorable teeth

Age

From **4 years** old to **9 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **24**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each individual, both the right and left primary molars in one jaw are included in the study.

Randomization (investigator's opinion)

Randomized

Randomization description

To ensure allocation concealment and reduce selection bias, a two-step sealed envelope randomization method was employed. For each participant, two sets of opaque, identical envelopes were prepared. In the first set, one envelope was labeled “R” (right) and the other “L” (left), indicating the side of the mouth. In the second set, one envelope was labeled “1” and the other “2”, representing the two intervention groups: Cold Ceramic and CEM cement. At the time of treatment, each participant was asked to randomly select one envelope from each set. The envelope drawn from the first set determined the tooth side (right or left) to be treated, while the envelope from the second set determined which material would be used on that side. Consequently, the opposite side received the alternative material. This method ensured that the assignment of the materials to each side was randomized and unbiased for each patient. The entire process was conducted by an independent operator not involved in the clinical procedures or outcome assessments.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the similarity of the preparation steps and the appearance of the two materials, the child participating in the study was unaware of the material used. After the study, the teeth treated with Cold Ceramic were named Group A and the teeth treated with CEM Cement were named Group B, and their results were reported to the statistician, as a result of which the statistician was unaware of the nature of each group.

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid beheshti university of medical sciences

Street address

Shahid Beheshti Dental School, Daneshjoo Boulevard, Evin, Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2025-07-26, 1404/05/04

Ethics committee reference number

IR.SBMU.DRC.REC.1404.023

Health conditions studied

1

Description of health condition studied

Pulpotomy of primary teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
clinical and radiographic success
Timepoint
6 month and 12 month
Method of measurement
Clinical examination including observation, percussion and palpation - radiographic examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pulpotomy with CEM Cement
Category
Treatment - Other

2

Description
Intervention group: Pulpotomy with Cold Ceramic
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Dental School
Full name of responsible person
Mobina Habibollahi
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Dentistry School, Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd., Evin, Shahid Chamran Highway, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin zarghi
Street address
Fifth Floor, Building No. 2 , Shahid Arabi Street, Yemen Street, Shahid Chamran Highway, Tehran
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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mobina Habibollahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data including participants' age, gender, and treatment outcomes are shared.

When the data will become available and for how long

Access begins 6 months after results are published.

To whom data/document is available

Researchers working in academic centers

Under which criteria data/document could be used

For further studies, please send an email

From where data/document is obtainable

Mobina Habibollahi mobina_habibollahi@sbmu.ac.ir

What processes are involved for a request to access data/document

Send an email introduction.

Comments