

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

Evaluation of effect of Bioactive Glass and Calcium-Enriched Mixture for Pulp Capping of Primary Teeth of children who referred to dental clinic

Protocol summary

Summary

Aims: The aim of this study is to evaluate pulpal response of primary teeth after direct pulp capping with two biocompatible materials, Calcium-Enriched Mixture and Bioactive Glass. **Design:** This study is done as randomized double blind. **Setting , conduct:** pulpotomy for 20 sound primary canines scheduled for orthodontic extraction. **Participants** including major eligibility criteria: Inclusion criteria: primary canines in children that had been scheduled for extraction due to their orthodontic treatment plan Exclusion criteria: root resorption more than the apical third, systemic complications, taking medications, spontaneous toothache and uncooperative children. **Intervention:** After mechanical pulp exposure, the exposed site is capped with either CEM cement or BAG randomly using a coin and then restored with amalgam. The samples are not informed about design of the study. The teeth are extracted after two months and examined histo- pathologically by a pathologist who is not informed about 2 groups. **Blinding** is done for participants and analyzer person. **main outcome measures:** Parameters of hard tissue bridge (HTB) formation, its type and quality as well as pulpal inflammation scores were compared between the two groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102033162N3**
Registration date: **2017-11-06, 1396/08/15**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-11-06, 1396/08/15

Registrant information

Name

Roza Haghgoo

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Center of Dental School of Shahed University

Expected recruitment start date

2016-07-15, 1395/04/25

Expected recruitment end date

2017-09-10, 1396/06/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of Bioactive Glass and Calcium-Enriched Mixture for Pulp Capping of Primary Teeth of children who referred to dental clinic

Public title

Bioactive Glass and Calcium-Enriched Mixture for Pulp Capping of Primary Teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: primary canines in children that had been scheduled for extraction due to their orthodontic treatment plan Exclusion criteria: root resorption more

than the apical third, systemic complications, taking medications, spontaneous toothache and uncooperative children

Age

From **7 years** old to **8 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Random table number used for randomization.

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

N4, Kargar Str, Enghelab Sq

City

Tehran

Postal code

Approval date

2015-12-20, 1394/09/29

Ethics committee reference number

41/357530

Health conditions studied

1

Description of health condition studied

pulpal histology

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pulpal inflammation, HTB

Timepoint

2 months

Method of measurement

Microscope

Secondary outcomes

1

Description

pulpal inflammation, HTB

Timepoint

2 months

Method of measurement

microscope

Intervention groups

1

Description

20 sound primary canines scheduled for orthodontic extraction, were selected. After mechanical pulp exposure, the exposed site was capped with either CEM cement or BAG and then restored with amalgam. The teeth were extracted after two months and examined histo- pathologically. Parameters of hard tissue bridge (HTB) formation, its type and quality as well as pulp inflammation scores were compared between the two groups. The data were analyzed using Fisher's exact test.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental School of Shahed University

Full name of responsible person

Roghieh Hojjati

Street address

N 71- Italia Str- Vesal Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Shahed University of
Medical Sciences

Full name of responsible person

Roghieh Hojjati

Street address

N71, Italia Str, Vesal Ave

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Shahed 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

Shahed University

Full name of responsible person

Roghieh Hojjati

Position

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Other areas of specialty/work

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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