Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 2026

Evaluating the effectiveness of indirect pulp capping of permanent molars using Protooth fast-setting calcium silicate cement and calcium hydroxide cement

Protocol summary

Study aim

Evaluating the effectiveness of indirect pulp capping of permanent molars using Protooth fast-setting calcium silicate cement and calcium hydroxide cement

Design

This study is designed as a split-mouth and the teeth will be intervened bilaterally in one person. One side will be randomly, flip the coin, capped with calcium hydroxide and the other tooth with protooth. In this study, the groups are parallel and the sample size of 124 teeth will be randomly divided into two groups of 62 teeth. This study will be double blind.

Settings and conduct

Tabriz dental faculty. All clinical procedures will be carried out by a post-graduate student of pediatric dentistry. The teeth will be randomly divided into two groups. On the teeth of the first group, protooth (Dentosolve, Aarhus, Denmark) is placed on the pulp floor with a thickness of 2 mm by the instrument and covered by wet cotton for 3 minutes. In the control group, a thin layer of calcium hydroxide cement (Hydro-C, Dentsply, York, PA, USA) is placed in the area by a condenser with a round end. Finally, the teeth are restored with composite.

Participants/Inclusion and exclusion criteria

Children with at least 2 permanent molars with active caries near the pulp on both sides of the jaw that require pulp coverage and restoration.

Intervention groups

This study is designed as a split-mouth and the teeth will be intervened bilaterally in one person. One side will be randomly capped with calcium hydroxide and the other tooth with protooth.

Main outcome variables

Absence of spontaneous and persistent pain; Absence of abscess or periapical fistula; Absence of sensitivity to Percussion test and chronic or acute periodontal inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161227031608N4**
Registration date: **2023-11-05, 1402/08/14**
Registration timing: **prospective**

Last update: **2023-11-05, 1402/08/14**
Update count: **0**

Registration date

2023-11-05, 1402/08/14

Registrant information

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Ali Vafaei
Name of organization / entity
Tabriz medical sciences university
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effectiveness of indirect pulp capping of permanent molars using Protooth fast-setting calcium silicate cement and calcium hydroxide cement

Public title

Evaluating the effectiveness of indirect pulp capping of permanent molars using Protooth fast-setting calcium silicate cement and calcium hydroxide cement

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children with at least 2 permanent molars with active caries near the pulp (with no pulp exposure) on both sides of the jaw Teeth required pulp coverage and restoration.

Exclusion criteria:

Teeth with spontaneous pain Teeth with abscess or periapical fistula

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **62**

More than 1 sample in each individual

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

Each patient must have at least 2 permanent molars with active caries on both sides to be randomly pulp capped with calcium hydroxide on one side and protooth the other side.

Randomization (investigator's opinion)

Randomized

Randomization description

Since the study will be split-mouth, by default, to randomize the treatments, the type of treatment for the teeth on the right side of the jaw arch will be determined by the "Flip the coin" method. The teeth on the left side of the jaw arch are in the second group and will receive another type of treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Another pediatric dentist with more than 10 years of experience who is unaware of the type of used substance, will judge the results without prior knowledge of the performed treatments as a third person.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht st., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.TBZMED.REC.1402.053

Health conditions studied

1

Description of health condition studied

Dental caries

ICD-10 code

K02

ICD-10 code description

Dental caries

Primary outcomes

1

Description

Spontaneous and persistent pain

Timepoint

Once 6 months after treatment

Method of measurement

Clinical examination

2

Description

Absence of abscess or periapical fistula

Timepoint

Once 6 months after treatment

Method of measurement

Clinical examination

3

Description

Absence of sensitivity to Percussion test and chronic or

acute periodontal inflammation

Timepoint

Once 6 months after treatment

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Protooth (Dentosolve, Aarhus, Denmark) is placed on the teeth with a 2 mm thick instrument and covered with wet cotton for 3 minutes. Then 2 mm thick glass ionomer cement (Fuji II, GC, America) is placed and cured for 20 seconds (Astralis 10, 650 mW/cm2, Ivoclar Vivadent, Schaan, Liechtenstein). Finally, the teeth are restored with composite.

Category

Treatment - Other

2

Description

Intervention group 2: A thin layer of calcium hydroxide cement (Hydro-C, Dentsply, York, PA, USA) is placed on the teeth by a condenser with a round end. Then 2 mm thick glass ionomer cement (Fuji II, GC, America) is placed. is given and cured for 20 seconds (Astralis 10, 650 mW/cm2, Ivoclar Vivadent, Schaan, Liechtenstein).Finally, the teeth are restored with composite.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz dental faculty

Full name of responsible person

Seyyede Shabnam Sajjadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Vice Chancellor of Research and Technology

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ali Vafaei

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available