Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of the effect of novel fast setting calcium silicate cement containing fluoride (Protooth) and Mineral Trioxide Aggregate in direct pulp capping of primary molars; A split mouth randomized controlled clinical trial

Protocol summary

Study aim
The effect of Protooth and Mineral Trioxide Aggregate in direct pulp capping of primary molars will be comprised with the aim of preservation of tooth vitality and structure and prevention of more aggressive treatments.

Design
In this randomized, single blind, split mouth,controlled clinical trial study with parallel group, symmetrical bilateral second primary molar teeth in maxilla or mandible will be chosen in 45 patients (overall 90 teeth).Randomization will be done by throwing a coin.

Settings and conduct
This clinical trial study will be done in Tabriz dentistry faculty. After obtaining informed consent from parient's parents,local anesthesia injection, isolation, and caries excavation, in group A, Protooth placement and in group B, MTA placement in exposure site will be performed. In this single blind study, participants are unaware of the allocation of study groups and information is not given to the parents about which of the materials is used in the patient's left or right primary molar.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 5 to 8 years old children having a pair of symmetric second primary molar teeth in one jaw having deep caries and vital pulp and no history of spontaneous pain; No sign of radiolucency or pathologic root resorption Exclusion criteria:Lack of informed consent by the child patient’s parent; Abnormal bleeding at the site of pulp exposure; No evidence of pulp exposure in teeth.

Intervention groups
Local anesthesia injection, isolation, and caries excavation will be performed in both groups and in group A, Protooth placement and in group B, MTA placement in exposure site will be performed. Then in both groups the site will be covered with Glass Ionomer. After amalgam restoration, periapical radiographs will be obtained.

Main outcome variables
Clinical success(Dental pulp vitality after treatment); Radiographic success.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100125003168N6**
Registration date: **2018-11-02, 1397/08/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-02, 1397/08/11**
Update count: **0**

Registration date
2018-11-02, 1397/08/11

Registrant information

Name
Leila Erfanparast

Name of organization / entity
Tabriz University of Medical sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-01, 1397/07/09

Expected recruitment end date
2019-10-01, 1398/07/09
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of novel fast setting calcium silicate cement containing fluoride (Protooth) and Mineral Trioxide Aggregate in direct pulp capping of primary molars; A split mouth randomized controlled clinical trial

Public title
Comparison of effect of Protooth and Mineral Trioxide Aggregate in Direct pulp capping of primary molars
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
5-8 years old children Having a pair of symmetric second primary molar teeth in one jaw having deep caries and vital pulp Capable of being restored by amalgam filling No history of spontaneous pain, pathologic mobility, draining sinus tract, redness or swelling of vestibule Normal gingival and periodontal condition, with no sensitivity to vestibular palpation, and no pain on percussion test Complete physical and mental health with no confounding history of systemic disease and/or use of special local or systemic drugs; No allergic reactions recorded in patient history No sign of radiolucency in periapical or furcation area No widening of PDL space or loss of lamina dura continuity No evidence of internal/external pathologic root resorption
Exclusion criteria:
Lack of informed consent by the child patient’s parent Abnormal bleeding at the site of pulp exposure (i.e. bleeding which lasts for more than 3 minutes) No evidence of pulp exposure at the site of caries excavation in symmetric second primary molar teeth, which were conventionally restored with an amalgam filling and excluded from our study Evidence of pulp exposure surrounded by carious dentin which is indicative of pulpal contamination
Age
From **5 years** old to **8 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **45**
More than 1 sample in each individual
Number of samples in each individual: **2**
90 teeth in 45 patients
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done by throwing a coin. One side of coin is assigned to the MTA and the other side is assigned to Protooth, and the first throw, determines the material used on the right primary molar of the patient.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, participants are unaware of the allocation of study groups and information is not given to the parents about which of the materials is used in the patient's left or right primary molar.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Commitee of Research Department - Tabriz University of Medical Sciences
Street address
Research Department- Tabriz University of Medical Sciences- Golgasht street- Tabriz- Iran
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2018-10-22, 1397/07/30
Ethics committee reference number
IR.TBZMED.REC.1397.621

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
Dental pulp vitality after treatment
Timepoint

6 &12 months

Method of measurement

Lack of any of clinical or radiographic signs or symptoms of treatment failure

Secondary outcomes

1

Description

Radiographic success

Timepoint

6&12 months

Method of measurement

Presence of one or more of the following radiographic signs will be considered as failure of treatment: internal and/or external root resorption, periodontal space widening, inter-radicular radiolucency, and periapical lesions.

2

Description

Clinical success

Timepoint

6 &12 months

Method of measurement

Presence of one or more of the following clinical signs/symptoms will be considered as failure of treatment: spontaneous pain, swelling, pathologic mobility, tenderness to pressure, and presence of sinus tract, swelling, and sensitivity to percussion.

Intervention groups

1

Description

Intervention group:The effect of Protooth (Ultrafast Protooth, Dentosolve, Aarhus, Denmark) in direct pulp capping of primary molars. This material was applied by using its own commercial instrument with a rounded tip in a layer with maximum thickness of 1.5 millimeters and then covered with a low viscosity Glass Ionomer layer (RMGI, Fuji II, LC GC, America) with a thickness of 2 mm to ensure the proper seal.

Category

Treatment - Other

2

Description

Control group: The effect of MTA (ProRoot; Dentsply, Tulsa, OK, USA) in direct pulp capping of primary molars. This material will be handled and applied to the exposure site with an MTA carrier, gently pressed with a moist cotton pellet for better adaptation with the exposure site, and then covered with a low viscosity Glass Ionomer layer (RMGI, Fuji II, LC GC, America) with a thickness of 2 mm to ensure the proper seal.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Department Of Pediatric Dentistry, Tabriz University of Medical Sciences

Full name of responsible person

Dr Leila Erfanparast

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Reasearch Vice-Chancellor- Tabriz University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Rashidi

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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

Reasearch Vice-Chancellor- 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

Dr Ali Vafaie

Position

Assisstant Professor of Pediatric Dentistry Department

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

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Latest degree

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The whole data is shareable.

When the data will become available and for how long

Access granted 6 months after publication of results

To whom data/document is available

Physicians and researchers in medical sciences as well as those involved in industry

Under which criteria data/document could be used

Data are released for non commercial purposes and for research objectives only.

From where data/document is obtainable

Dr.Niloofar Azima Pediatric dentistry department, Tabriz dental faculty, Tabriz University of medical sciences, Golgasht street. niloofar_azima@yahoo.com 04133346977

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

The applicant should forward their application to the email provided. the data will be send via email at 72 hours at most.

Comments