Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of TheraCal-LC® and Mineral Trioxide Aggregate in direct pulp capping of primary molars in 5-8 year old children. A split-mouth randomized controlled clinical Trial .

Protocol summary

Summary

1) Objectives: In the current study, the effect of TheraCal LC® and Mineral Trioxide Aggregate (MTA) 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. 2) Design: For this split mouth randomized controlled clinical trial study, symmetrical bilateral second primary molar teeth in maxilla or mandible will be chosen in 45 patients (overall 90 teeth). 3) Participants: 5-8 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 root resorption, and absence of any abnormal bleeding at the site of pulp exposure. 4) Setting and conduct: In each patient one of the bilateral second primary molars will be allocated to group “A” and the other one to group “B” randomly (45 teeth in each group). 5) Intervention: Local anesthesia injection, isolation, and caries excavation will be performed and in group 'A", TheraCal-LC placement and light curing and in group "B", MTA placement and Glass Ionomer lining will be performed. After amalgam restoration, final periapical radiographs will be immediately obtained. 6) Main outcome measures: Patients will be followed up periodically at 6 and 12 months after the procedure and in each follow up session clinical and radiographic evaluations will be performed by two experienced pediatric dentists who are blinded to the procedure applied in each group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201602063168N3**
Registration date: **2017-02-10, 1395/11/22**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name
Leila Erfanparast
Name of organization / entity
Tabriz University of Medical sciences
Country
Iran (Islamic Republic of)
Phone
+98 41 1335 5965
Email address
erfanparastl@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Technology Department of Tabriz University of Medical Sciences

Expected recruitment start date

2016-10-06, 1395/07/15

Expected recruitment end date

2017-10-07, 1396/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of TheraCal-LC® and Mineral Trioxide Aggregate in direct pulp capping of primary molars in 5-8 year old children. A split-mouth randomized controlled clinical Trial .

Public title
Comparison of the effect of TheraCal-LC® and Mineral Trioxide Aggregate in direct pulp capping of primary molars in 5-8 year old children.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 5-8 years old children; 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; Having a pair of symmetric second primary molar teeth in one jaw having deep caries and vital pulp which is 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; 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; No evidence of pulp exposure at the site of caries excavation in 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; Abnormal bleeding at the site of pulp exposure (i.e. bleeding with dark color which lasts for more than 3 minutes despite application of wet cotton pellet with mild pressure).

Age
From **3 years** old to **8 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
For this split mouth randomized controlled clinical trial study, symmetrical bilateral second primary molar teeth in maxilla or mandible were chosen in each patient according to the inclusion criteria. In each patient one of the bilateral second primary molars was allocated to group "A" (i.e. TheraCal-LC group) and the other one to group "B" (MTA group) randomly.

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

Postal code

Approval date
2016-12-26, 1395/10/06

Ethics committee reference number
IR.TBZMED.REC.1395.994

Health conditions studied

1

Description of health condition studied
dental caries

ICD-10 code
K02.1

ICD-10 code description
Caries of dentine

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
Study group: The effect of TheraCal LC (Bisco Inc., Schamburg, IL, USA) 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 light-cured for 20 seconds.
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
Street address
Department Of Pediatric Dentistry, Tabriz University of Medical Sciences, Golgasht street
City
Tabriz

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
Street address
Golgasht street, Tabriz University of Medical Sciences, Reasearch Vice-Chancellor
City
Tabriz
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
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
Dentistry faculty, Tabriz University of Medical Sciences
Full name of responsible person
Dr Ali Vafai
Position
Assisstant Professor of Pediatric Dentistry Department
Other areas of specialty/work
Street address
Pediatric Dentistry department,Dentistry faculty, Tabriz University of Medical Sciences , Golgasht street, Tabriz
City
Tabriz
Postal code
Phone
+98 41 3335 5965
Fax
Email
alivafaiitbzmed@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Dentistry faculty, Tabriz University of Medical

Sciences

Full name of responsible person

Dr Leila Erfanparast

Position

Associate Proffessor of Pediatric Dentistry department

Other areas of specialty/work

Street address

Pediatric Dentistry department, Dentistry faculty, Tabriz University of Medical Sciences, Golgasht street, tabriz

City

Tabriz

Postal code

Phone

+98 41 3335 5965

Fax

Email

leilaerfan@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Dentistry faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr Parastoo Iranparvar Alamdari

Position

Postgraduate student of pediatric dentistry

Other areas of specialty/work

Street address

Pediatric dentistry department, Dentistry faculty, Tabriz University of Medical Sciences, Golgasht street, Tabriz

City

Tabriz

Postal code

Phone

00

Fax

Email

parastoo_iranparvar@yahoo.com

Web page address

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