Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison clinical and radiographic success rate of TheraCal-LC® and Mineral Trioxide Aggregate in pulpotomy of primary teeth with 12 month follow up: A split-mouth randomized controlled clinical Trial

Protocol summary

Study aim

The effect of TheraCal-LC® and Mineral Trioxide Aggregate in pulpotomy 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 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, TheraCal-LC® 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 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.

Intervention groups

Local anesthesia injection, isolation, and caries excavation and access cavity will be performed in both groups and in group A, TheraCal-LC® 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

نام اختصاری Stainless Steel Crowns سه حرف SSC نام.است
استو MTAسه حرف Mineral Trioxide Aggregate اختصاری

IRCT registration information

IRCT registration number: **IRCT20100125003168N7**
Registration date: **2020-03-03, 1398/12/13**
Registration timing: **prospective**

Last update: **2020-03-03, 1398/12/13**
Update count: **0**

Registration date

2020-03-03, 1398/12/13

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

2020-04-05, 1399/01/17

Expected recruitment end date

2020-04-15, 1399/01/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison clinical and radiographic success rate of TheraCal-LC® and Mineral Trioxide Aggregate in pulpotomy of primary teeth with 12 month follow up: A split-mouth randomized controlled clinical Trial

Public title

Comparison success rate of TheraCal-LC® و Mineral Trioxide Aggregate in pulpotomy of primary teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

-Complete physical and mental health, with no confounding history of allergic reactions and systemic disease and/or use of special local or systemic drugs Having a pair of symmetric primary molar teeth (first or second) in one jaw, having deep caries and vital pulp which is capable of being restored by SSC 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 5-8 years old children 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 with dark color which lasts for more than 5 minutes despite application of wet cotton pellet with mild pressure)

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 TheraCal-LC® 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

2020-02-29, 1398/12/10

Ethics committee reference number

IR.TBZMED.RES.1398.1252

Health conditions studied

1

Description of health condition studied

Reversible Pulpitis

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

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:
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
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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
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Associate Proffessor of Pediatric Dentistry department
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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.Sedigheh Hasanpour, Pediatric dentistry department, Tabriz dental faculty, Tabriz University of medical sciences, Golgasht street. s_hasanpour87@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