Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of clinical and radiographic success and failure of Mineral Trioxide Aggregate (MTA) and Cold ceramic in pulp therapy of mandibular primary molars with reversible pulpitis in 3-6 years old children: a randomized clinical trial

Protocol summary

Study aim

Comparative study of the clinical and radiographic success and failure of Mineral Trioxide Aggregate (MTA) and cold ceramic in treating the pulp of mandibular second molars with reversible pulpitis.

Design

Parallel-group, double-blind, randomized, phase 2-3 clinical trial on 50 patients. A table of random numbers was used for randomization.

Settings and conduct

In children who refer to the pediatric dental clinic for treatment of pulp in mandibular second molar teeth with reversible pulpitis, after initial radiography, pulpotomy treatment is performed with a standard protocol. Pulp chamber seal is done for each patient using Mineral Trioxide Aggregate (MTA) or cold ceramic. then if there are no signs and symptoms of treatment failure, the final restoration is done with Stainless Steel Crown (SSC). Clinical evaluation of treatment results of 3, 6 and 12 months and radiographic evaluations are performed in 6 and 12 month periods. The patient and the evaluator of the treatment results will not know what substance was used to flood the canal in each patient

Participants/Inclusion and exclusion criteria

Patients who do not have any systemic diseases such as congenital or rheumatic heart disease, leukemia, allergic reactions to substances such as local anesthetics and latex, do not need general anesthesia and sedation, have good individual and family cooperation. deep caries with pulp exposure during caries removal.

Intervention groups

Intervention A: The remaining pulp is covered with paste MTA (cerkamed medical company poland). Intervention B: The remaining pulp is covered with cold ceramic paste (Sarv Javaid modares, Iran).

Main outcome variables

The percentage of occurrence of pain; sensitivity to accuracy; swelling; pathological laziness; root lucency; internal or external root analysis; Widening of the Periodontal Ligament (PDL); bone loss; and lamina dura integrity

General information

Reason for update

According to endodontic and pediatric professors, reversible pulpitis is correct term.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230719058851N1**
Registration date: **2023-07-27, 1402/05/05**
Registration timing: **prospective**

Last update: **2024-05-31, 1403/03/11**
Update count: **3**

Registration date

2023-07-27, 1402/05/05

Registrant information

Name
Faeze Azizi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-08-06, 1402/05/15
Expected recruitment end date
2023-10-07, 1402/07/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of clinical and radiographic success and failure of Mineral Trioxide Aggregate (MTA) and Cold ceramic in pulp therapy of mandibular primary molars with reversible pulpitis in 3-6 years old children: a randomized clinical trial

Public title
Evaluation of clinical and radiographic success and failure of Mineral Trioxide Aggregate (MTA) and Cold ceramic in pulp therapy of mandibular primary molars with reversible pulpitis in 3-6 years old children: a randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
The presence of two-thirds of the root length in terms of radiography; and lack of radiographic evidence of pulp degeneration, such as internal or external root resorption, furca radiolucency, intraradicular or periapical bone destruction, pulp stones. Includes patients who have no systemic diseases such as congenital or rheumatic heart disease, leukemia, allergic reactions to substances such as local anesthetics and latex. They have good individual and family cooperation, deep pitted lesions whose pulp is exposed during caries removal.
Exclusion criteria:
The presence of any clinical and radiographic symptoms indicating pulpal degeneration or physiological analysis of more than 2/3 of the root (imminence of tooth loss) non-physiological analysis of the root or possibility of proper tooth restoration.
Age
From **3 years** old to **6 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, a simple method using a table of random numbers will be used to randomly select people; In this way, first, the order "AB" is considered for the odd number, and the order "BA" is considered for the even number. Then we refer to the table, choose a column randomly and if the first selected number is odd, we use the order 'AB'; In this way, the first person in group A will receive Mineral Trioxide Aggregate treatment and the next person will receive cold ceramic treatment spontaneously in group B. In the same way, if the number obtained is even, consider the order of BA and the first person will be placed in group B and receive cold ceramic treatment, and the next person will automatically be placed in group A and receive Mineral Trioxide Aggregate treatment. This work is repeated for 25 times to get 25 samples in each group.
Blinding (investigator's opinion)
Double blinded
Blinding description
Clinical and radiographic evaluations are performed by a person who does not know the type of substance used in each group. - The patient will not know the type of material used in each tooth.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Islam university of medical science
Street address
Pajoohesh blvd
City
Ilam
Province
Ilam
Postal code
6967114459
Approval date
2023-07-17, 1402/04/26
Ethics committee reference number
IR.MEDILAM.REC.1402.111

Health conditions studied

1

Description of health condition studied
Mandibular molars reversible pulpitis
ICD-10 code
K04.0
ICD-10 code description
Pulpitis

Primary outcomes

1

Description
Frequency of pain in treated molars
Timepoint
3,6 and 12 months after treatment
Method of measurement
The history of the presence or absence of spontaneous pain after the treatment is asked from the patient. (Yes/No)

2

Description
The frequency of occurrence of sensitivity to dex in treated primary molars
Timepoint
3,6 and 12 months after treatment
Method of measurement
During a clinical examination with a precision test, the patient is asked if there is any sensitivity or not

3

Description
The frequency of occurrence swelling in treated primary molars
Timepoint
3,6 and 12 months after treatment
Method of measurement
A clinical examination is performed to detect the presence or absence of swelling

4

Description
The frequency of occurrence fistula in treated primary molars
Timepoint
3,6 and 12 months after treatment
Method of measurement
A clinical examination is performed to detect the presence or absence of fistula.

5

Description
The frequency of occurrence pathologic mobility in treated primary molars
Timepoint
3,6 and 12 months after treatment
Method of measurement
A clinical examination is performed to detect the presence or absence of pathologic mobility.

6

Description
The frequency of occurrence of root lucency in radiographic images in treated primary molars
Timepoint
6 and 12 month after treatment
Method of measurement
Radiographic examination is performed to detect the presence or absence of lucency around the root

7

Description
The frequency of occurrence of internal resorbtion in radiographic images in treated primary molars
Timepoint
6 and 12 month after treatment
Method of measurement
Radiographic examination is performed to detect the presence or absence of internal resorbtion

8

Description
The frequency of occurrence of external resorbtion in radiographic images in treated primary molars
Timepoint
6 and 12 month after treatment
Method of measurement
Radiographic examination is performed to detect the presence or absence of external resorbtion

9

Description
The frequency of occurrence of PDL widening in radiographic images in treated primary molars
Timepoint
6 and 12 month after treatment
Method of measurement
Radiographic examination is performed to detect the presence or absence of PDL widening

10

Description
The frequency of occurrence of bone resorbtion in radiographic images in treated primary molars
Timepoint
6 and 12 month after treatment
Method of measurement
Radiographic examination is performed to detect the presence or absence of bone resorbtion

11

Description
The frequency of occurrence of lamina dura disintegration in radiographic images in treated primary molars
Timepoint
6 and 12 month after treatment
Method of measurement
Radiographic examination is performed to detect the presence or absence of lamina dura disintegration

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group A:First, a periapical radiograph will be prepared from the desired tooth using the standard parallel technique with the help of Rinne xcp (dentsply, USA). Film number zero is used with speed E (Kodak, Ekta speed) or speed F (Kodak, Insigne). Then appropriate local anesthesia is performed using lidocaine 2% and epinephrine 1:80000 (Darou pakhsh, Tehran, Iran) and then the surface of the tooth is primed with chlorhexidine 0.2% (Shahre Daru, Tehran, Iran) and the coronal caries are removed by providing isolation with rubberdam under sterile conditions and with an Angle No. 4 burr.In the next step, the roof of the pulp chamber is removed with a 330 high speed bur along with water spray and the coronal access hole is completed. Using a large process bur (No. 6), the coronal pulp is completely removed from the entrance of the canals and the pulp chamber is washed with normal saline. Hemostasis will be achieved at the site of coronal pulp excision, on the entrance of the canals, using a sterile cotton ball moistened with normal saline within 5 minutes (2,3,5). If homeostasis is not achieved, the patient is excluded from the study. The remaining pulp is covered with two millimeters of paste (cerkamed Medical Company Poland) MTA+. which will be obtained by mixing the powder with sterile saline at a ratio of 3:1 and is covered. A layer of zonalin (Golchadent company) is temporarily placed and the patient is visited again seven days later (short term follow up). Before placing the Stainless Steel Crown (SSC), the operator first checks the clinical signs, pain, sensitivity to impact, swelling, laxity and fistula. In the absence of the mentioned cases, the tooth will be repaired with SSC. The patient will not know the type of material used in each tooth.

Category

Treatment - Other

2

Description

Intervention group B : Intervention group A:First, a periapical radiograph will be prepared from the desired tooth using the standard parallel technique with the help of Rinne xcp (dentsply, USA). Film number zero is used with speed E (Kodak, Ekta speed) or speed F (Kodak, Insigne). Then appropriate local anesthesia is performed using lidocaine 2% and epinephrine 1:80000 (Darou pakhsh, Tehran, Iran) and then the surface of the tooth is primed with chlorhexidine 0.2% (Shahre Daru, Tehran, Iran) and the coronal caries are removed by providing isolation with rubberdam under sterile conditions and with an Angle No. 4 burr.In the next step, the roof of the pulp chamber is removed with a 330 high speed bur along with water spray and the coronal access hole is completed. Using a large process bur (No. 6), the coronal pulp is completely removed from the entrance of the canals and the pulp chamber is washed with normal saline. Hemostasis will be achieved at the site of coronal pulp excision, on the entrance of the canals, using a sterile cotton ball moistened with normal saline within 5 minutes (2,3,5). If homeostasis is not achieved, the patient is excluded from the study. The remaining pulp is covered with three millimeters of paste cold ceramic is covered. A layer of zonalin (Golchadent company) is temporarily placed and the patient is visited again seven days later (short term follow up). Before placing the Stainless Steel Crown (SSC), the operator first checks the clinical signs, pain, sensitivity to impact, swelling, laxity and fistula. In the absence of the mentioned cases, the tooth will be repaired with SSC. The patient will not know the type of material used in each tooth.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Pediatric dental clinic

Full name of responsible person
Shirin Marzughi

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ilam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Maryam kazempour

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6931851147

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info@medilam.ac.ir

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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
Ilam University of Medical Sciences
Full name of responsible person
Shirin Marzughi
Position
Assistante professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Faeze azizi
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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
No - There is not 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
All data will be shareable
When the data will become available and for how long
Access period 6 months after publication of results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
No other conditions are required

From where data/document is obtainable

Contact via mail : faezeazizi96@gmail.com

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

As soon as the request is received, the documents will be provided to the requester within a week

Comments