

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparative evaluation of clinical & radiographic success & failure rate of Mineral Trioxide Aggregate (MTA) & Biodentine in pulp therapy of second mandibular primary molar with irreversible pulpitis in 3-6 years old children

Protocol summary

Study aim

Comparative assessment of clinical and radiographic success and failure of Mineral Trioxide Aggregate (MTA) and Biodentine in pulp therapy of second mandibular primary molar with irreversible pulpitis

Design

A double-blind clinical trial with parallel groups, phase 2-3 on 50 patients. Randomization was done using random numbers table.

Settings and conduct

In children who are referred to the Pediatric dentistry department of dentistry faculty of Isfahan with mandibular second primary molar teeth with irreversible pulpitis, pulpectomy with standard protocol is performed after providing initial radiographic assessment. Sealing of the canals is provided using either Mineral Trioxide Aggregate (MTA) or Biodentine in each patient. After 1 week, Stainless Steel Crown (SSC) is placed as the final restoration. The clinical and radiographic evaluation will be done after 3, 6, and 12-months. None of the patients or outcome assessors will be aware of the type of material used for treatment in each patient.

Participants/Inclusion and exclusion criteria

-Inclusion criteria: Having a vital second mandibular primary molar tooth with deep caries lesion in the crown that is not extended subgingivally more than 1 mm with irreversible pulpitis indicated for Pulpectomy -Exclusion criteria: Presence of any clinical or radiographic sign of pulpal degeneration/ physiologic root resorption more than 2/3 of the root length/ non-physiologic root resorption/ non-restorable tooth

Intervention groups

Intervention: remaining pulp is sealed with Biodentine paste (Septodont, Saint-Maur-des-Fosses Cedex, France)
Control: remaining pulp is sealed with MTA+ paste (CERKAMED Medical Company Poland)

Main outcome variables

Frequency of pain; sensitivity to concussion; swelling; pathologic mobility; radiographic lucency; internal and external root resorption; Periodontal Ligament (PDL) widening; bone loss; loss of lamina dura

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210419051016N1**

Registration date: **2021-08-09, 1400/05/18**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-09, 1400/05/18**

Update count: **0**

Registration date

2021-08-09, 1400/05/18

Registrant information

Name

Maryam Hajiahmadi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of clinical & radiographic success & failure rate of Mineral Trioxide Aggregate (MTA) & Biodentine in pulp therapy of second mandibular primary molar with irreversible pulpitis in 3-6 years old children

Public title

Evaluation of success & failure of Mineral Trioxide Aggregate (MTA) & Biodentine in pulp therapy of second mandibular primary molar with irreversible pulpitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

No underlying systematic diseases which leads to inhibition of local anesthesia injection Having a vital second mandibular primary molar tooth with deep caries lesion in the crown that is not extended subgingivally more than 1 mm Having the history of typical pain related to the irreversible pulpitis (patient's chief complaint is spontaneous pain that lasts more than multiple seconds) Sensitivity to thermal stimuli All teeth are vital and the operator evaluates the pulp vitality by visual observation of pulp hemorrhage from all root canals of the intended tooth Having access to the participant for 12-months follow-up Pulp exposure due to severe carious crown No pathologic mobility No abscess, fistula, or swelling related to the intended tooth Possibility of restoration with Stainless Steel Crown (SSC) Possibility of providing hemostasis in the orifice entrance No internal or pathologic external root resorption No periapical radiolucency No widening in the periodontal ligament No radiolucency in furcation area No calcific degeneration of the pulp No root resorption more than 1/3 of the root length

Exclusion criteria:

Patients with underlying systemic disorders, physical, or mental disabilities Presence of any clinical or radiographic sign of pulpal degeneration including severe hemorrhage from root canals that making hemostasis impossible in 5 minutes, internal root resorption, bone resorption in furcation or preapical area, swelling or sinus tract formation, and pulp necrosis Physiologic root resorption more than 2/3 of the root length (the sign of exfoliation) Non-physiologic root resorption Non-restorable tooth

AgeFrom **3 years** old to **6 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **50****Randomization (investigator's opinion)**

Randomized

Randomization description

In the present study, simple allocation will be the method of choice for random allocation of the patients. In this method, the 'AB' order is considered for each odd number, and the 'BA' order is considered for each even number. Then a column is randomly selected from the table and if the first selected number is odd, the 'AB' order is applied which means the first patient is allocated in the A group and receives MTA treatment, and as a result, the next patient is allocated to the B group and receives Biodentine treatment. Similarly, If the selected number is even, the 'BA' order is applied and the first patient is allocated in the B group and receives Biodentine treatment, and as a result, the next patient is allocated to the A group and receives MTA treatment. This is done 25 times until 25 samples are reached in each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

-Outcome assessor was not aware of the type of material used for each tooth while evaluating the treated teeth clinically and radiographically -Patients were not aware of the type of material used for their treatment

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

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Pediatric Dentistry department, Dentistry Faculty, Isfahan University of Medical Sciences, Hezar-jerib St.

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81746-73461

Approval date

2021-05-26, 1400/03/05

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Irreversible pulpitis of second mandibular primary molar

ICD-10 code

K04.0

ICD-10 code description

Pulpitis

Primary outcomes

1

Description

Frequency of incidence of pain in sealed second mandibular primary molar

Timepoint

3, 6, and 12 months after treatment

Method of measurement

Patient is asked about a history of spontaneous pain after treatment (yes/no question)

2

Description

Frequency of incidence of sensitivity to concussion in sealed second mandibular primary molar

Timepoint

3, 6, and 12 months after treatment سه، شش و 12 ماه پس از درمان

Method of measurement

Patient is asked about the presence of sensitivity while doing concussion test (yes/no question)

3

Description

Frequency of incidence of swelling in sealed second mandibular primary molar

Timepoint

3, 6, and 12 months after treatment

Method of measurement

Patient is evaluated clinically for the presence of swelling (yes/no)

4

Description

Frequency of incidence of fistula formation in sealed second mandibular primary molar

Timepoint

3, 6, and 12 months after treatment

Method of measurement

Patient is evaluated clinically for the presence of fistula (yes/no)

5

Description

Frequency of incidence of pathologic mobility in sealed second mandibular primary molar

Timepoint

3, 6, and 12 months after treatment

Method of measurement

Patient is evaluated clinically for the presence of pathologic mobility (yes/no)

6

Description

Frequency of incidence of lucency around the root in radiographic imaging in sealed second mandibular primary molar

Timepoint

6 and 12 months after treatment

Method of measurement

Patient is evaluated radiographically for the presence of lucency around the root (yes/no)

7

Description

Frequency of incidence of internal root resorption in radiographic imaging in sealed second mandibular primary molar

Timepoint

6 and 12 months after treatment

Method of measurement

Patient is evaluated radiographically for the presence of internal root resorption

8

Description

Frequency of incidence of external root resorption in radiographic imaging in sealed second mandibular primary molar

Timepoint

6 and 12 months after treatment

Method of measurement

Patient is evaluated radiographically for the presence of external root resorption

9

Description

Frequency of incidence of widening of the Periodontal Ligament (PDL) in radiographic imaging in sealed second mandibular primary molar

Timepoint

6 and 12 months after treatment

Method of measurement

Patient is evaluated radiographically for the presence of widened PDL

10

Description

Frequency of incidence of bone loss in radiographic imaging in sealed second mandibular primary molar

Timepoint

6 and 12 months after treatment

Method of measurement

Patient is evaluated radiographically for the presence of bone loss

11**Description**

Frequency of incidence of loss of lamina dura in radiographic imaging in sealed second mandibular primary molar

Timepoint

6 and 12 months after treatment

Method of measurement

Patient is evaluated radiographically for the presence of loss of lamina dura

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group A: Firstly, periapical radiographic imaging with paralleling technique is provided using Rinne XCP (DENTSPLY, USA) film holder and size 0 film with either E speed (Kodak, Ekta speed) or F speed (Kodak, insigne). Then proper local anesthesia injection is done using Lidocaine 2% and Epinephrine 1:80000 (Darou pakhsh, Tehran, Iran), and preparation of the tooth surface is done with 0.2% chlorhexidine (Shahre Daru, Tehran, Iran) is provided. after isolation with a rubber dam, coronal caries is removed using a sterile carbide round no.4 bur. Then, a high-speed 330 bur is used for removing the roof of the pulp chamber and access cavity preparation is completed. Afterward, by using a large round bur (no.6) coronal pulp tissue is removed completely from the canal orifices and the pulp chamber is then rinsed using sterile normal saline. Hemostasis is provided by applying saline-impregnated sterile cotton for 5 minutes. If bleeding is not controlled, the patient will be excluded from the study. To seal the canals and prevent bacterial invasion, the remaining pulp is covered with 2mm of MTA+ paste (CERKAMED Medical Company Poland) which is prepared by mixing the powder with sterile saline with 3:1 proportions. A layer of zonaline (Golchadent company) is placed as a provisional restoration. The patient will be recalled 7 days after treatment and if there would not be any sign or symptoms of treatment failure including pain, sensitivity to concussion, swelling, mobility, and fistula Stainless Steel Crown will provide the final restoration for the given tooth.

Category

Treatment - Other

2**Description**

Intervention group B: Firstly, periapical radiographic imaging with paralleling technique is provided using Rinne XCP (DENTSPLY, USA) film holder and size 0 film with either E speed (Kodak, Ekta speed) or F speed (Kodak, insigne). Then proper local anesthesia injection is done using Lidocaine 2% and Epinephrine 1:80000 (Darou pakhsh, Tehran, Iran), and preparation of the tooth surface is done with 0.2% chlorhexidine (Shahre Daru, Tehran, Iran) is provided. after isolation with a rubber dam, coronal caries is removed using a sterile carbide round no.4 bur. Then, a high-speed 330 bur is used for removing the roof of the pulp chamber and access cavity preparation is completed. Afterward, by using a large round bur (no.6) coronal pulp tissue is removed completely from the canal orifices and the pulp chamber is then rinsed using sterile normal saline. Hemostasis is provided by applying saline-impregnated sterile cotton for 5 minutes. If bleeding is not controlled, the patient will be excluded from the study. To seal the canals and prevent bacterial invasion, the remaining pulp is covered with 3 mm of Biodentine (Septodont, Saint-Maur-des-Fosses Cedex, France). A layer of zonaline (Golchadent company) is placed as a provisional restoration. The patient will be recalled 7 days after treatment and if there would not be any sign or symptoms of treatment failure including pain, sensitivity to concussion, swelling, mobility, and fistula Stainless Steel Crown will provide the final restoration for the given tooth.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Pediatric Dentistry department/ Dentistry Faculty of Isfahan University of Medical Sciences

Full name of responsible person

Dr. Maryam Hajjahmadi

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Sponsors / Funding sources**1****Sponsor**

Name of organization / entity

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Full name of responsible person

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Maryam Hajjahmadi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Pediatric Dentist

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Person responsible for scientific inquiries

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Name of organization / entity

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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
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
Title and more details about the data/document
All data will be available
When the data will become available and for how

long
Starting 6 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
No other conditions
From where data/document is obtainable
Please send the request to "mona.esmaili.p@gmail.com"
What processes are involved for a request to access data/document
Documents will be sent in 1 week after receiving the request
Comments
No more information