Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 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

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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
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 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
Street address
Pediatric Dentistry department, Dentistry Faculty, Isfahan University of Medical Sciences, Hezar-jerib St.
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Approval date
2021-05-26, 1400/03/05
Ethics committee reference number

IR.MUI.RESEARCH.REC.1400.078

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity

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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
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Position
Assistant professor

Latest degree
Specialist

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

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