Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of clinical and radiographic success of MTA، cold ceramic and 3-mix in the pulpotomy of mandibular second molars: randomized clinical trial

Protocol summary

Study aim

Determining the clinical and radiographic success of MTA (mineral trioxide aggregate) cold ceramic, and triple antibiotic paste in the pulpotomy of mandibular second molars

Design

A controlled, double-blind, randomized, phase 2 clinical trial with parallel groups on 100 patients. The randomization function of Excel software was used for randomization.

Settings and conduct

In this study, 120 patients were randomly divided into 3 treatment groups with 40 patients in each group. 5-8-year-old children of both sex which visit the pediatric section of Isfahan Dental University participated in this study. following getting access to the pulp chamber and removing pulp tissue, 2 mm of MTA, Cold Ceramic, and 3-Mix will be put on the pulp canal. The teeth will be restored with glass ionomer and a stainless steel crown. The patients will be prescribed to come for recall in 3,6,12 months, assessing clinical and radiographical indexes of treated teeth.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.5-8 year old children 2.having at least 1 primary second molar with the indication of pulpotomy 3.The teeth must not have pathological signs such as spontaneous pain, pathological luxation, internal resorption ,External resorption,PDL widening, inter-radicular radiolucency , Calcific metamorphosis. 4.The teeth must be score 1 of PAI index exclusion criteria : 1.systemic disease 2. physical and mental limitations 3. extra canal bleeding 4.sinus tract/swelling 5.pulp necrosis 6. allergic to the treatment 7. not cooperative in follow up sessions

Intervention groups

MTA, Cold Ceramic, 3-Mix

Main outcome variables

Clinical success, defined by the absence of pain, swelling, abscess, sinus tract, and pathological mobility. Radiographic success, defined by the absence of furcation/periapical radiolucency and pathological root resorption.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260309068976N1**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

Registration date

2026-08-08, 1405/05/17

Registrant information

Name

nazanin Nasr

Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-30, 1405/05/08

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of clinical and radiographic success of MTA، cold ceramic and 3-mix in the pulpotomy of mandibular second molars: randomized clinical trial

Public title
Comparison of three different materials used for nerve treatment of lower second baby teeth in children?
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
5-8 year old children having at least 1 primary second molar with the indication of pulpotomy The teeth must not have pathological signs such as spontaneous pain, pathological luxation, internal resorption ,External resorption,PDL widening, inter-radicular radiolucency , Calcific metamorphosis. Does not have a periapical lesion
Exclusion criteria:
Systemic problems Physical and mental limitations Inability to properly restore the tooth, Sensitivity to therapeutic materials Patient's failure to attend follow-up appointments
Age
From **5 years** old to **8 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly allocated to one of the three treatment groups (MTA, Cold Ceramic, or 3Mix) using block randomization with a 1:1:1 allocation ratio. A computer-generated randomization sequence with fixed or variable block sizes will be prepared by an independent researcher not involved in patient recruitment or treatment. Allocation concealment will be ensured using sequentially numbered, opaque, sealed envelopes that will be opened only after the participant has been enrolled.
Blinding (investigator's opinion)
Double blinded
Blinding description
participants, healthcare providers (Physicians, nurses, physiotherapists, etc.) who care for participants during the trial, data collectors, and outcome assessors.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Faculties of Dentistry, Health and Modern Medical Technologies, Isfahan University of Medical Scienc
Street address
Hazar Jarib Ave.
City
Esfahan
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Isfehan
Postal code
81746-73461
Approval date
2026-07-27, 1405/05/05
Ethics committee reference number
IR.MUI.DHMT.REC.1405.082

Health conditions studied

1

Description of health condition studied
Pulpotomy، Triple antibiotic paste، clinical Trial، primary teeth، bioceram، MTA Angelus
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Clinical success of pulpotomy in mandibular second primary molars treated with Mineral Trioxide Aggregate (MTA), Cold Ceramic, or 3Mix antibiotic paste, assessed by the absence of spontaneous pain, swelling, sinus tract, pathological mobility, and tenderness to percussion.
Timepoint
3,6,12 months
Method of measurement
Clinical scoring table

2

Description
Radiographic success of pulpotomy in mandibular second primary molars treated with Mineral Trioxide Aggregate

(MTA), Cold Ceramic, or 3Mix antibiotic paste, assessed by the absence of furcation/periapical radiolucency and pathological internal or external root resorption.

Timepoint
6,12 months

Method of measurement
Radiographic scoring table

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Pulpotomy of mandibular second primary molars using Cold Ceramic as the pulpotomy agent. Following coronal pulp removal and hemostasis, Cold Ceramic is placed over the radicular pulp, and the tooth is restored according to the study protocol.

Category
Treatment - Drugs

2

Description
Intervention group 2: Pulpotomy of mandibular second primary molars using Mineral Trioxide Aggregate (MTA) as the pulpotomy agent. After coronal pulp removal and hemostasis, MTA is placed over the radicular pulp, followed by restoration according to the study protocol.

Category
Treatment - Drugs

3

Description
Intervention group 3: Pulpotomy of mandibular second primary molars using 3Mix antibiotic paste as the pulpotomy agent. After coronal pulp removal and hemostasis, 3Mix paste is applied over the radicular pulp, followed by restoration according to the study protocol.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Isfahan universty of medical sciences

Full name of responsible person
Nazanin Nasr

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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
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
Nazanin Nasr

Position
Pediatric post graduate student

Latest degree
Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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