

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### Evaluation and comparison of the effectiveness of mineral trioxide aggregate and cold ceramic in the success of primary molars pulpotomy: a clinical and radiographic study

#### Protocol summary

##### Study aim

Evaluation and Comparison of Mineral Trioxide Aggregate and coldceramic in Primary Tooth Pulpotomy: Clinical and Radiographic Study

##### Design

Clinical trial with control group and intervention groups, with parallel, randomized groups, phase 4 on 42 patients

##### Settings and conduct

This clinical trial study was performed at Ahvaz Jundishapur University to compare the success of pulpotomy treatment of deciduous molars with cold ceramic and mineral trioxide aggregate in 42 children aged 4 to 9 years, each with two deciduous molars for treatment. The pulpotomy is performed with mineral trioxide aggregate and a glass ionomer light cure is placed on it and finally a metal crown is placed. Then they are evaluated clinically and radiographically in 3 and 6 month follow-up. Participants, outcome assessors, and the person responsible for data collection are not aware of the allocation of the intervention group. The researcher is aware of the allocation of groups, but does not choose the material by himself.

##### Participants/Inclusion and exclusion criteria

General and mental health of the child  
Lack of clinical adverse symptoms in the target tooth  
Lack of adverse radiographic signs in the target tooth  
Failure to refer the patient for 3 and 6 month follow-up  
Having an underlying disease

##### Intervention groups

In the intervention group, cold ceramic material is used for primary molar pulpotomy. In the control group, standard material mineral trioxide aggregate (mta) is used for primary molar palpotomy.

##### Main outcome variables

Evaluation of the success rate of primary molar pulpotomy with mineral trioxide aggregate  
Evaluation of the success rate of primary molar pulpotomy with

Coldceramic

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220426054664N1**

Registration date: **2022-05-31, 1401/03/10**

Registration timing: **prospective**

Last update: **2022-05-31, 1401/03/10**

Update count: **0**

##### Registration date

2022-05-31, 1401/03/10

##### Registrant information

##### Name

Bitarasteh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 4352 4848

##### Email address

bitarasteh@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-10, 1401/03/20

##### Expected recruitment end date

2022-07-11, 1401/04/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation and comparison of the effectiveness of mineral trioxide aggregate and cold ceramic in the success of primary molars pulpotomy: a clinical and radiographic study

**Public title**

Coldceramic in primary Tooth Pulpotomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

General and mental health of the child  
Lack of clinical adverse symptoms in the target tooth such as spontaneous pain or nocturnal pain, swelling of pulpal origin, pathological sagging, fistula  
Lack of adverse radiographic signs of the desired tooth such as internal root resorption, external root resorption and periapical or furca area

**Exclusion criteria:**

Failure to refer the patient for 3 and 6 month follow-up  
Having an underlying disease

**Age**

From **4 years** old to **9 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **2**

One primary molar pulpotomy with mineral trioxide aggregate and another primary molar in the same person pulpotomy with Coldceramic

**Randomization (investigator's opinion)**

N/A

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Participants enter the study with their consent but do not know each tooth with which material was pulpotomized. The clinical caregiver treats primary pulpotomy but is unaware of the type and purpose of the study. Evaluators evaluate the clinical outcome and radiographs of treated teeth. They know the purpose of the study , but they do not know the type of material used for each pulpotomy treatment and group assignment. The person responsible for collecting the data is also unaware of the type of intervention and the type of substance used to treat the pulpotomy and to assign groups. Data analysts are aware of the type of intervention and group

allocation.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Ahwaz University of Medical Sciences

**Street address**

No:14. Damavand7 building. Esfahan. Dey Street

**City**

Ahwaz

**Province**

Khouzestan

**Postal code**

6381944814

**Approval date**

2022-01-01, 1400/10/11

**Ethics committee reference number**

IR.AJUMS.REC.1400.589

**Health conditions studied****1****Description of health condition studied**

pulpotomy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Success of pulpotomy treatment

**Timepoint**

Follow-up 3 and 6 months after treatment

**Method of measurement**

Radiographs and clinical examination

**Secondary outcomes**

empty

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

Intervention group: Treatment of primary molar

pulpotomy with cold ceramic , which is made in Iran and contains compounds of calcium oxide, silicon acid, these compounds are 93% of its components. Other components include MgO, MnO, Fe2O3, Na2O, K2O and TiO2. (First, anesthesia is performed in a child who is eligible for the study, and then tooth decay is removed and accessed, and cervical molar pulpotomy is performed and placed on wet cotton pulp for five minutes for homeostasis, then wet cotton. It is removed and the cold-ceramic powder is mixed with sterile serum in a ratio of 1: 1. When the paste is formed, it is placed on a pulp that has already been homeostasized, and glass ionomer light is placed on it and cured for 40 seconds, and finally the metal is coated. It is used as a permanent repair

#### Category

Treatment - Drugs

## 2

#### Description

Control group: Treatment of primary molar pulpotomy with mineral trioxide aggregate, Made in Iran and contains compounds of tricalcium silicate, dicalcium silicate, tricalcium aluminate, tetracalcium aluminophyte, calcium sulfate and bismuth oxide. (First, anesthesia is performed in a child who is eligible for the study, and then tooth decay is removed and accessed, and cervical molar pulpotomy is performed and placed on wet cotton pulp for five minutes for homeostasis, then wet cotton. It is removed and the mineral trioxide aggregate powder is mixed with sterile serum in a ratio of 1: 1. When the paste is formed, it is placed on a pulp that has already been homeostasized, and glass ionomer light is placed on it and cured for 40 seconds, and finally the metal is coated. It is used as a permanent repair.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ahwaz Jundishapur University

##### Full name of responsible person

Bitarasteh

##### Street address

No:14, Damavand7 building, Esfahan, Dey Street

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

6381944814

##### Phone

+98 61 4352 4848

##### Email

Bitarasteh99@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahwaz University of Medical Sciences

##### Full name of responsible person

Bitarasteh

##### Street address

No:14 , Damavand7 building, Esfahan, Dey street

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

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##### Email

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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

Ahwaz 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

Ahwaz University of Medical Sciences

##### Full name of responsible person

Bitarasteh

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Dentistry

##### Street address

No.14, damavand 7 building, Esfahan, Dey street

##### City

Ahwaz

##### Province

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##### Postal code

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+98 61 4352 4848

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**Email**

bitarasteh99@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Bitarasteh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Bitarasteh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

**Street address**

No.14, damavand 7 building, Esfahan, Dey street

**City**

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**Province**

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**Postal code**

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**Phone**

+98 61 4352 4848

**Fax**

**Email**

bitarasteh99@gmail.com

## 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

Evaluation and Comparison of Mineral Trioxide

Aggregate and coldceramic in Primary Tooth Pulpotomy:

Clinical and Radiographic Study

### When the data will become available and for how long

Start the access period at the same time as printing the results

### To whom data/document is available

for everyone

### Under which criteria data/document could be used

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### From where data/document is obtainable

bitarasteh992@gmail.com

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

Send the request via email and receive a response within a month

### Comments