Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Bita Rasteh

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
Bita Rasteh
Street address
No:14، Damavand7 building، Esfahan، Dey Street
City
Ahwaz
Province
Khouzestan
Postal code
6381944814
Phone
+98 61 4352 4848
Email
Bitarasteh99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Bita Rasteh
Street address
No:14 ، Damavand7 building، Esfahan، Dey street
City
Ahwaz
Province
Khouzestan
Postal code
6381944814
Phone
+98 61 4352 4848
Email
Bitarasteh99@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Bita Rasteh
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
Khouzestan
Postal code
6381944814
Phone

+98 61 4352 4848

Fax

Email

bitarasteh99@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Bita Rasteh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

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

City

Ahvaz

Province

Khouzestan

Postal code

63819448114

Phone

+98 61 4352 4848

Fax

Email

bitarasteh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Bita Rasteh

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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Khouzestan

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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

کو

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