Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of pulpotomized primary molar teeth using Calcium-Enriched Mixture and Ferric sulfate clinically and radiographically in children: a randomized clinical trial

Protocol summary

Study aim

Comparison of clinical and radiographic success rate and pain after pulpotomy in primary molars using Calcium-Enriched Mixture (CEM) cement and Ferric sulfate

Design

Clinical trial with intervention groups, with parallel, two-way blind and randomized groups on 24 patients. Simple randomization method (flip the coin) will be used to randomize.

Settings and conduct

This project will be carried out in the Department of Pediatrics of the Kerman Dentistry School. Before treatment, the patient becomes aware completely of two types of material used for treatment, but he/she does not know which substance is used for her/his tooth during treatment. Follow up evaluations are carried out by two researchers who are not aware of the type of treatment and they will comment on radiographic criteria. The statistician is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: pulp exposure due to caries; restorable teeth with stainless steel crown; hemostasis could be easily achievable. Non inclusion criteria: pathologic mobility; history of spontaneous pain; sinus tracts; abscess or swelling; internal or pathologic external root resorptionan; interradicular or periapical radiolucency.

Intervention groups

Intervention group 1: CEM cement. This material is combined according to the manufacturer's instructions and placed on the pulp. Intervention group 2: Ferric sulfate. 15.5% ferric sulfate is placed on the pulp for 15 seconds. It is then washed and zonalin base is placed in the pulp chamber.

Main outcome variables

Internal resorption; dental abscess and fistula

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171020036896N8**
Registration date: **2020-06-26, 1399/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-26, 1399/04/06**
Update count: **0**

Registration date

2020-06-26, 1399/04/06

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32119023

Email address

sajadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2020-07-10, 1399/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of pulpotomized primary molar teeth using Calcium-Enriched Mixture and Ferric sulfate clinically and radiographically in children: a randomized clinical trial

Public title
Clinical and radiographic success and pain after pulpotomy treatment using Calcium-Enriched Mixture and Ferric sulfate

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pulp exposure due to caries Restorable teeth with stainless steel crown Hemostasiscould be easily achievable

Exclusion criteria:
Pathologic mobility History of spontaneous pain Sinus tracts , abscess or swelling Internal or pathologic external root resorptionan Interradicular or periapical radiolucency

Age
From **3 years** old to **9 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the simple randomization method (flip the coin) will be used. In such a way that one of the study groups will be considered as heads and the other group will be considered as tails. Then the same number of coins will be thrown based on the sample size. Finally, to prevent disclosure of random sequencing, the allocation concealment will be used.

Blinding (investigator's opinion)
Double blinded

Blinding description
Before treatment, the patient becomes aware completely of two types of material used for treatment, but he/she does not know which substance is used for her/his tooth during treatment. Follow up evaluations are carried out by two researchers who are not aware of the type of treatment and they will comment on radiographic criteria. The statistician is not aware of the type of treatment.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Shafa avenue

City
Kerman

Province
Kerman

Postal code
7618759689

Approval date
2014-12-06, 1393/09/15

Ethics committee reference number
IR.KMU.REC.1393.538

Health conditions studied

1

Description of health condition studied
Pulpitis

ICD-10 code
Pulpitis

ICD-10 code description
Pulpits

Primary outcomes

1

Description
Internal resorption

Timepoint
6 months after the start of intervention

Method of measurement
Through radiographic examination

2

Description
Dental abscess and fistula

Timepoint
6 months after the start of intervention

Method of measurement
Through clinical examination

Secondary outcomes

1

Description
External resorption

Timepoint
6 months after the start of the intervention
Method of measurement
Through radiographic examination

2

Description
Furcation radiolucency
Timepoint
6 months after the start of the intervention
Method of measurement
Through radiographic examination

Intervention groups

1

Description
Intervention group 1: After pulpotomy, the CEM cement was prepared according to the manufacturer's instructions and placed in the pulp chamber.
Category
Treatment - Drugs

2

Description
Intervention group 2: a cotton ball impregnated by ferric sulfate 15.5% was placed on the orifices of canals for 15 seconds.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry
Full name of responsible person
Farzaneh Jalalih
Street address
Shafa Ave
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 8074
Email
fznjalali@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
Shafa avenue
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 8074
Email
fznjalali@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Farzaneh Jalali
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shafa avenue
City
Kerman
Province
Kerman
Postal code
7618759689
Phone
+98 34 3211 8074
Email
fznjalali@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Farzaneh Jalali

Position
resident

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Shafa avenue

City
Kerman

Province
Kerman

Postal code
7618759689

Phone
+98 34 3211 8074

Email
fznjalali@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Farzaneh Jalali

Position
resident

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Shafa avenue

City
Kerman

Province
Kerman

Postal code
7618759689

Phone
+98 34 3211 8074

Email
fznjalali@gmail.com

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