

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### Comparison of the success rate of pulpectomy with CEM cement pulpotomy in primary molars; A multicenter Randomized Clinical Trial

#### Protocol summary

##### Study aim

To compare clinical and radiographic success rates of Metapex pulpectomy and Calcium-Enriched Mixture (CEM) Cement pulpotomy in primary molars with inflamed radicular pulp

##### Design

This is a randomized, blinded, multicenter (two universities and three operators) clinical trial with a parallel group design. The initial sample size was calculated to be 100 teeth.

##### Settings and conduct

This study will be conducted in the clinics of pediatric dentistry departments of Mashhad and Yazd University of Medical Sciences. Children and their parents/caregivers will be blinded. The operators can not be blinded due to the nature of the treatments. The outcome assessors and data analyzer will also be blinded. Three pediatric dentistry residents will conduct clinical treatments. Eligible teeth will be selected and after pulp exposure following caries removal the coronal pulp will be amputated. If the pulp stumps shows the evidence of inflammation, the teeth will then be definitely included in the study and will be randomly allocated into 2 intervention groups: CEM Cement pulpotomy and Metapex pulpectomy. Following pulp therapy, the teeth will be restored with stainless steel crowns and will be followed 6, 12, 18 and 24 months postoperatively.

##### Participants/Inclusion and exclusion criteria

Pediatric patients aged 4-9 years Primary molars with vital pulps and deep carious lesions Presence of inflamed radicular pulp after pulp amputation (sever bleeding may be present that can be controlled up to 10 minutes) Tenderness to percussion or spontaneous pain may be present

##### Intervention groups

CEM cement pulpotomy Metapex Pulpectomy

##### Main outcome variables

Clinical and radiographic success of the treated teeth

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201226049838N1**

Registration date: **2021-01-12, 1399/10/23**

Registration timing: **retrospective**

Last update: **2021-01-12, 1399/10/23**

Update count: **0**

##### Registration date

2021-01-12, 1399/10/23

##### Registrant information

##### Name

Sedigheh Sabbagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3806 7100

##### Email address

sabbaghds@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-07-05, 1396/04/14

##### Expected recruitment end date

2019-03-20, 1397/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the success rate of pulpectomy with CEM cement pulpotomy in primary molars; A multicenter Randomized Clinical Trial

### Public title

Comparison of pulpectomy with CEM cement pulpotomy in primary molars

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Pediatric patients aged 4-9 years Primary molars with vital pulps and deep carious lesions Presence of inflamed radicular pulp after pulp amputation (sever bleeding may be present and can be controlled up to 10 min) Tenderness to percussion or spontaneous pain may be present

#### Exclusion criteria:

Evidence of Pulp necrosis Pathologic internal or external root resorption Pathologic mobility Pulp canal obliteration

### Age

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

### Gender

Both

### Phase

4

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization of teeth will be done by simple randomization method using a web-based randomization service ([www.randomizer.org](http://www.randomizer.org)). The generated list of random numbers will be kept by those other than the operators.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Children and their parents/caregivers will be blinded, they will not know to which group they belong. The operators can not be blinded due to the nature of the treatments. The clinical outcome assessors will be those other than operators and they will be unaware of the treatment provided to each patient. The radiographic outcome assessors can not be blinded due to the nature of treatments. The data analyzer will just be informed about the aims of the research. He will not know which data set is belong to which group.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Daneshgah street, Goreishi building

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

#### Approval date

2017-06-21, 1396/03/31

#### Ethics committee reference number

IR.mums.sd.REC.1394.242

## Health conditions studied

### 1

#### Description of health condition studied

inflamed radicular pulp of primary molars which is the indication for pulpectomy treatment

#### ICD-10 code

K04.0

#### ICD-10 code description

Pulpitis

## Primary outcomes

### 1

#### Description

Clinical success rate of CEM cement pulpotomy and Metapex pulpectomy

#### Timepoint

6, 12 months

#### Method of measurement

spontaneous pain, Tenderness to percussion and palpation, gingival swelling, presence of sinus tract/fistula, pathologic mobility

### 2

#### Description

Radiographic success rate of CEM cement pulpotomy and Metapex pulpectomy

#### Timepoint

6, 12 months

#### Method of measurement

Internal root resorption, pathologic external root resorption, furcal/periapical radiolucencies, pulp canal obliteration, periodontal ligament widening, Pathologic

involvement of succedaneous tooth

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: CEM cement pulpotomy: following coronal pulp amputation, hemostasis will be attempted (up to 10 minutes), then CEM cement (BioniqueDent, Tehran, Iran) paste will be inserted to the pulp chamber to cover pulp stumps. The rest of the cavity will then be filled with light-cured resin-modified glass ionomer cement and the tooth will be restored permanently with stainless steel crown.

#### Category

Treatment - Other

### 2

#### Description

Intervention group: Metapex Pulpectomy: radiographic working length will be determined and radicular pulp will be extirpated. The canals will be dried with paper points. Root canals will be then filled with Metapex (Calcium Hydroxide + Iodoform) (Meta Biomed Co., Ltd, Korea). The rest of the cavity will be then filled with light-cured resin-modified glass ionomer cement and the tooth will be restored permanently with stainless steel crown.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

The clinic of Pediatric dentistry department of Mashhad University of Medical Sciences

##### Full name of responsible person

Alireza Sarraf Shirazi

##### Street address

Vakilabad Blvd

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3806 7100

##### Email

sarrafa@mums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

The clinic of Pediatric dentistry department of Shahid Sadoughi University of Medical Sciences

##### Full name of responsible person

Zahra Bahrololoumi

##### Street address

Imam Reza Blvd

##### City

Yazd

##### Province

Yazd

##### Postal code

0000000000

##### Phone

+98 35 3625 5881

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zbahrololoom@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Saeed Asgary

##### Street address

Daneshjoo Blvd-Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1983963113

##### Phone

+98 21 2242 7752

##### Email

saasgary@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti University of Medical Sciences

#### Proportion provided by this source

30

#### 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

### 2

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Sarraf Shirazi

**Street address**

School of Dentistry, Vakilabad Blvd

**City**

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**Phone**

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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**

Mashhad University of Medical Sciences

**Proportion provided by this source**

70

**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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Saeed Asgary

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Iranian Center for Endodontic Research -Daneshjoo Blvd-Velenjak

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Alireza Sarraf Shirazi

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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**Phone**

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**Email**

sarrafa@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Sedigheh Sabbagh

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3806 7100

**Email**

sedigheh.sabbagh@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Will be sent on demand of individual researchers

**Study Protocol**

No - There is not a plan to make this available  
**Statistical Analysis Plan**  
No - There is not a plan to make this available  
**Informed Consent Form**  
No - There is not 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**  
No - There is not a plan to make this available  
**Data Dictionary**  
No - There is not a plan to make this available