

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparative study of clinical and radiographic outcomes of indirect pulp treatment with silver diamine fluoride versus calcium hydroxide in primary teeth: a randomized controlled clinical trial.

#### Protocol summary

##### Study aim

Comparative determination of clinical and radiographic outcomes of indirect pulp treatment with silver diamine fluoride and calcium hydroxide in primary teeth

##### Design

Clinical trial with intervention groups, with parallel groups, triple blind, randomized, phase 2 on 66 patients. Random Allocation Software was used for randomization.

##### Settings and conduct

Children with indication of indirect pulp treatment referred to pediatric dentistry department are divided into two groups (calcium hydroxide and silver diamine fluoride) and after complete removal of peripheral caries, experimental materials are placed on the remaining caries. Clinical and radiographic symptoms will be checked after 3 and 6 months. The outcome assessor will be a statistical analyst and the patients will be blinded.

##### Participants/Inclusion and exclusion criteria

3-7-year-old children without systemic disease with Frankel 3 and 4, with large carious lesions, caries close to the pulp, lamina dura, and normal periodontal ligament space, absence of periapical changes and pathological analysis.

##### Intervention groups

In both groups, a deep injection of local anesthesia is performed. The decay of the outer walls of the cavity is completely removed. In the inner walls, the caries are completely removed and some of the caries remain to prevent pulp exposure. After removing the caries in one group, calcium hydroxide in the deepest part of the cavity, meter is placed. In the other group, silver diamine fluoride is applied to the floor of the cavity. After placing the test material, the tooth is subsequently restored with RMGI to ensure proper flooding in each case, and then the final restoration is done with SSC.

##### Main outcome variables

Normal gums, no abscess and fistula, no pain in the

desired tooth, no internal and external analysis, no expansion of the periodontal ligament space, no furca involvement and no apical lucency.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230530058338N1**

Registration date: **2023-06-11, 1402/03/21**

Registration timing: **prospective**

Last update: **2023-06-11, 1402/03/21**

Update count: **0**

##### Registration date

2023-06-11, 1402/03/21

##### Registrant information

##### Name

Shahram Mosharrafian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 919 857 8366

##### Email address

shahramosharrafian@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-06, 1402/04/15

##### Expected recruitment end date

2024-05-04, 1403/02/15

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparative study of clinical and radiographic outcomes of indirect pulp treatment with silver diamine fluoride versus calcium hydroxide in primary teeth: a randomized controlled clinical trial.

**Public title**

Pulp effect with silver diamine fluoride and calcium hydroxide in primary teeth

**Purpose**

Treatment

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

Children without systemic disease who are cooperative according to Frankel classification, Frankel 3 and 4. On clinical examination, large carious lesions involving the occlusal or proximal surfaces, with normal gingival appearance and having at least one decayed deciduous molar on each side of the mandible or maxilla. In the radiographic examination, the observation of caries close to the pulp that involved about two-thirds of the thickness of the dentin, normal lamina dura, normal periodontal ligament space, root length more than two-thirds, absence of periapical changes, absence of external or internal pathological analysis.

**Exclusion criteria:**

A history of sharp, piercing pulpal pain that persists after removal of the stimulus, as well as spontaneous pain and nocturnal pain Clinical examination showing tooth mobility, tooth discoloration, sinus tract or tooth abscess Radiographic examination showing a carious lesion with intermittent exposure of the pulp, interrupted lamina dura, widening of the periodontal ligament space, periapical radiolucency and internal or external pathological degeneration. Children with absolute sensitivity to any kind of anesthetic

**Age**

From **3 years** old to **7 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **66**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Since the two groups are supposed to have the same sample size, limited randomization and block randomization will be used in this study. Random block units will usually be used in order to balance the number of samples allocated to each of the studied groups. The size of the blocks will be chosen randomly and in each

block there is an equal number of each group. The way to make the random sequence will be by the computer software "Random Allocation Software". Concealment of random allocation will be done by using opaque sealed and waxed envelopes in a random sequence by an independent person who is not aware of the study process.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The outcome assessor and the statistical analyst will not know about the study groups. In the case of patients, blinding is such that patients do not know which material was used to cover the pulp. In the case of the assessor, the person who completes the study checklist, they do not know the patients group. The data analyst will be blinded and all data will be coded.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of dentistry faculty, Tehran university of medical sciences

**Street address**

Deputy of Research and Technology of Tehran university of medical sciences, corner of Qods, Keshavarz Blvd

**City**

Tehran

**Province**

Tehran

**Postal code**

1416633591

**Approval date**

2023-06-10, 1402/03/20

**Ethics committee reference number**

IR.TUMS.DENTISTRY.REC.1402.022

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

Large caries of primary teeth

**ICD-10 code**

K08.43

**ICD-10 code description**

Partial loss of teeth due to caries

## Primary outcomes

### 1

#### Description

Normal gums

#### Timepoint

After 3 and 6 months

#### Method of measurement

Clinical assessment

### 2

#### Description

Absence of abscess and fistula

#### Timepoint

After 3 and 6 months

#### Method of measurement

Clinical assessment

### 3

#### Description

Absence of desired toothache

#### Timepoint

After 3 and 6 months

#### Method of measurement

Clinical assessment

### 4

#### Description

No internal and external degeneration

#### Timepoint

After 6 months

#### Method of measurement

Radiographic evaluation

### 5

#### Description

Lack of widening of the periodontal ligament space

#### Timepoint

After 6 months

#### Method of measurement

Radiographic evaluation

### 6

#### Description

No furca involvement

#### Timepoint

After 6 months

#### Method of measurement

Radiographic evaluation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: A deep injection of local anesthesia is performed using lidocaine and the tooth is isolated with a cotton roll. The caries removal of the outer walls of the cavity is completely performed by a diamond process bur using a high speed handpiece with plenty of water. In the inner walls, the infected caries are completely removed and some of the affected caries remain to prevent pulp exposure. After removing the caries, in one group, self-cure calcium hydroxide from Dycal Calcium Hydroxide brand (Dentsply sirona-USA)) is placed in the deepest part of the cavity with a minimum thickness of 1.5 mm by using a Dykal applicator.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: A deep injection of local anesthesia is performed using lidocaine and the tooth is isolated with a cotton roll. The caries removal of the outer walls of the cavity is completely performed by a diamond process bur using a high speed handpiece with plenty of water. In the inner walls, the infected caries are completely removed and some of the affected caries remain to prevent pulp exposure. After removing the caries, In the other group, SDF Cariestop 30% (Biodinamica-Brazil) was applied to the cavity floor with a microtip applicator.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of pediatric dentistry, Tehran University of Medical Sciences

##### Full name of responsible person

Shahram Mosharrafian

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##### Province

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##### Email

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## Sponsors / Funding sources

1

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Akbar Fotouhi

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vcr@sina.tums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Shahram Mosharrafiān

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Position**

Assistant Professor

**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Negar Ziaee

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dentistry

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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**

Not applicable