

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

Street address

Tehran university of medical sciences, corner of Qods, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416633591

Phone

+98 21 8889 6696

Email

shahramosharrafian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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

Phone

+98 21 8889 6696

Email

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

Street address

Tehran university of medical sciences, corner of Qods, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416633591

Phone

+98 21 8889 6696

Email

shahramosharrafiān@yahoo.com

Person responsible for scientific 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

Street address

Tehran university of medical sciences, corner of Qods, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416633591

Phone

+98 21 8889 6696

Email

shahramosharrafiān@yahoo.com

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

Street address

Tehran university of medical sciences, corner of Qods, Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1416633591

Phone

+98 21 8889 6696

Email

Negar.ziaee2015@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

Not applicable