

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Influence of silver diamine fluoride application with and without light curing on arresting early childhood caries and effect on oral health related quality of life: randomized clinical control

#### Protocol summary

##### Study aim

Despite increasing attention to preventive dentistry, the prevalence of ECC is still high. Many of caries remain untreated at this young age because of uncooperative child and lack of treatment facilities for treatment under general anesthesia. These untreated caries can affect the quality of life of the child and his parents. SDF is known to be effective in arresting dentinal caries in deciduous teeth. In this study, the effect of SDF application with different protocols on arresting the decay process and also the effect of this treatment on the oral health related quality of life in children and their parents will be measured.

##### Design

Random clinical trial with parallel, double-blind groups. A list of random numbers will be used for randomization.

##### Settings and conduct

Children are randomly divided into two groups using a list of random numbers. In each group, for each individual, two eligible molar teeth are treated with SDF. In the first group, the SDF application time will be 1 minute and in the second group, 30 seconds. One tooth per person is randomly irradiated with light cure for 40 seconds after SDF application. oral health status, arrest of dental caries and quality of life are assessed at each follow-up. arrest of caries by tactile examination is assessed by dentist who is blinded about the group of dental treatment.

##### Participants/Inclusion and exclusion criteria

Children between 2-4 years of age with active dentin caries (ICDAS 6) without symptomatic involvement or pulp necrosis without significant systemic disease (ASA I and II) who are unable to cooperate with routine dental treatment

##### Intervention groups

One side of the patient's mouth will be exposed to light cure after SDF application and the other side will only be

treated with SDF.

##### Main outcome variables

arrest of early childhood caries in children, oral health related quality of life.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170305032881N2**

Registration date: **2022-04-19, 1401/01/30**

Registration timing: **retrospective**

Last update: **2022-04-19, 1401/01/30**

Update count: **0**

##### Registration date

2022-04-19, 1401/01/30

##### Registrant information

##### Name

Zahra Mohammadzadeh

##### Name of organization / entity

Mashhad dental school

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3662 9015

##### Email address

mohammadzadehz@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Influence of silver diamine fluoride application with and without light curing on arresting early childhood caries and effect on oral health related quality of life: randomized clinical control

**Public title**

effect of silver diamine fluoride with or without the use of light cure

**Purpose**

Prevention

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

Children between 2-4 years without significant systemic disease (ASA I and II) who are unable to cooperate in routine dental treatment. Lack of sensitivity to SDF ingredients Consent of parents / caregivers to their child's participation in the study Presence of at least 2 teeth / 1 pair of deciduous molars with dentin caries lesion (ICDAS 6) active without signs of involvement or pulp necrosis child cooperation for SDF application and parents' desire to follow the next follow-ups and follow the oral health instructions

**Exclusion criteria:**

Severely non-cooperative patients for whom application of SDF is not possible. Children with sensitivity to SDF content Children with deep exposed caries

**Age**

From **2 years** old to **4 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

a paired of caries molar teeth

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A list of random numbers will be created using the [WWW.randomizer.org](http://WWW.randomizer.org) site. A simple randomization method will be used dental assistant who is not participating in the study will have a list of random numbers and will determine the side of the light cure treatment.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A dental assistant who does not participate in the study will have a list of random numbers and will determine the side of the light cure treatment .and Will register as a code. IN follow-up sessions, the evaluator will be blinded about which side belongs 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**

Department of Pediatric Dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences,Vakil Abad Blvd, Mashhad,Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Approval date**

2021-12-05, 1400/09/14

**Ethics committee reference number**

IR.MUMS.DENTISTRY.REC.1400.121

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

early childhood caries

**ICD-10 code**

K02.1

**ICD-10 code description**

پوسیدگی گسترده دندانهای شیری که به عاج رسیده اما درگیری پالپ ایجاد نکرده است

**Primary outcomes****1****Description**

caries arrest

**Timepoint**

1 month,3 months,6 months

**Method of measurement**

visual and tactile assessment

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: SDF with light curing on caries primary molar

#### Category

Treatment - Drugs

### 2

#### Description

Control group: SDF without light curing on caries primary molar

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry ,Mashhad university of Medical Sciences

##### Full name of responsible person

Zahra Mohammadzadeh

##### Street address

Department of pediatric dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences, Vakil Abad Blvd, Mashhad, Iran.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3882 9500

##### Email

mohammadzadehz@mums.ac.ir

##### Web page address

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Hossein Bagheri

##### Street address

Department of pediatric dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences, Vakil Abad Blvd, Mashhad, Iran.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3882 9500

##### Email

mohammadzadehz@mums.ac.ir

##### 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

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

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr Zahra Mohammadzadeh

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

##### Street address

Department of pediatric dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences, Vakil Abad Blvd, Mashhad, Iran.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948959

##### Phone

+98 51 3882 9500

##### Email

mohammadzadehz@mums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Zahra Mohammadzadeh

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Department of pediatric dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences, Vakil Abad Blvd, Mashhad, Iran.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3882 9500

**Email**

mohammadzadehz@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Zahra Mohammadzadeh

**Position**

assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Department of pediatric dentistry, Faculty of Dentistry, Mashhad University of Medical Sciences, Vakil Abad Blvd, Mashhad, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948959

**Phone**

+98 51 3882 9501

**Email**

mohammadzadehz@mums.ac.ir

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

Yes - There is a plan to make this available

**Study Protocol**

No - There is not 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**

comparison the arrest of dental caries

**When the data will become available and for how long**

6 months after paper publication

**To whom data/document is available**

academic researcher

**Under which criteria data/document could be used**

At the reasonable request of researchers, raw study information will be provided to them

**From where data/document is obtainable**

By sending an email to the corresponding author

**What processes are involved for a request to access data/document**

as soon as possible after sending email

**Comments**