

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### Comparison of the effect of fluoride varnish with silver diamine fluoride on oral pH in the period of primary teeth in children with Sever-Early Childhood Caries (S-ECC)

#### Protocol summary

##### Study aim

Determining the effect of silver diamine fluoride on oral pH  
Determining the effect of fluoride varnish on oral pH  
Comparison of the effect of silver diamine fluoride and fluoride varnish on oral pH

##### Design

A clinical trial study with a control group Fluoride varnish group (control group) silver diamine fluoride group (intervention group) Samples will be assigned to two random groups using the random number generation method by Random Number Generator software. In this way, random numbers in the range (0,1) will be generated in the software and numbers less than 0.5 will be assigned to the silver diamine fluoride group and numbers greater than 0.5 to the Fluoride varnish group (and vice versa). These two substances will be purchased from Pooyesh Teb Atieh Company.

##### Settings and conduct

In this clinical trial study that will be performed in a private office and clinic in Zanjan, a number of children are divided into two groups: fluoride varnish and silver diamine fluoride.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: The child should be between 2 and 4 years old (have a deciduous tooth system in the age range), have a complication of premature tooth decay, the patient's parents should cooperate well and be aware of the side effects of silver diamine fluoride. Exclusion criteria: The child has any systemic disease, any mental disability, herpes and herpes and dry mouth.

##### Intervention groups

The first group is given 5% fluoride varnish (V-varnish / Korea / fluoride varnish / 0.4 ml) under the brand name V-varnish. For the second group, 30% silver diamine fluoride (SDF) (cariestop30% / Iran / biodinamica / ml5) is used.

##### Main outcome variables

Immediately after SDF application, 5 minutes later, after 10 minutes, after 20 minutes, and after 30 minutes, oral pH was measured and recorded using paper.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210718051926N1**

Registration date: **2021-08-15, 1400/05/24**

Registration timing: **prospective**

Last update: **2021-08-15, 1400/05/24**

Update count: **0**

##### Registration date

2021-08-15, 1400/05/24

##### Registrant information

##### Name

bahareh nazemi salman

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3341 2597

##### Email address

dr.b.nazemi@gmail.com

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2021-08-20, 1400/05/29

##### Expected recruitment end date

2021-09-15, 1400/06/24

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effect of fluoride varnish with silver diamine fluoride on oral pH in the period of primary teeth in children with Sever-Early Childhood Caries (S-ECC)

**Public title**

pH in children

**Purpose**

Prevention

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

patients without systemic disease Severe early childhood caries (SECC)

**Exclusion criteria:**

parents forbidden

**Age**

From 2 years old to 4 years old

**Gender**

Both

**Phase**

3

**Groups that have been masked***No information***Sample size**

Target sample size: 38

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be assigned to two random groups using the random number generation method by Random Number Generator software. In this way, random numbers in the range (0,1) will be generated in the software and numbers less than 0.5 will be assigned to the SDF group and numbers greater than 0.5 to the NaF group (and vice versa).

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of zanzan university of medical sciences

**Street address**

Zanzan university of medical sciences ,gavazang ave,  
zanzan town

**City**

Zanzan

**Province**

Zanzan

**Postal code**

۴۵۱۵۶۱۳۱۹۱

**Approval date**

2021-07-24, 1400/05/02

**Ethics committee reference number**

IR.ZUMS.REC.1400.145

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

dental caries

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

oral pH

**Timepoint**

0-5-10-20-30 minutes after intervention

**Method of measurement**

pH-indicator paper

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Silver diamine fluoride will be used once. Then at 5, 10, 20 and 30 minutes after the intervention, children's oral pH will be measured using pH paper.

**Category**

Prevention

**2****Description**

Control group: fluoride varnish will be used once. Then at 5, 10, 20 and 30 minutes after the intervention, children's oral pH will be measured using pH paper.

**Category**

Prevention

**Recruitment centers**

## 1

### Recruitment center

**Name of recruitment center**

Pediatric dentistry center

**Full name of responsible person**

Bahareh Nazemi Salman

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Aftab buliding, Ghalee Ave, Zanjan

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## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Alireza Shoghli

**Street address**

Central building of Zanjan university of medical sciences, Jomhori eslami Blvd, Zanjan

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shoghli@zums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Zanjan 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**

Zanjan University of Medical Sciences

**Full name of responsible person**

Bahareh Nazemi Salman

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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## Person responsible for scientific inquiries

### Contact

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Specialist

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

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## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The complete data file includes personal information such as gender and age and study information such as the type of intervention and the measured outcomes of the final outcome.

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

The results and the resulting article can be shared immediately after publication.

**To whom data/document is available**

All people

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

Mentioning the source and the city and the people who did the work, any analysis is allowed.

**From where data/document is obtainable**

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09191439740 bahareh nazemi salman:  
dr.b.nazemi@gmail.com: 09123777185

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

In case of phone call or e-mail and explaining the reason for requesting the data and guarantee for future reference, the data will be sent at the earliest opportunity. Of course, provided that the preliminary results are published

**Comments**