

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 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 zanjan university of medical sciences

Street address

Zanjan university of medical sciences ,gavazang ave,
zanjan town

City

Zanjan

Province

Zanjan

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

Street address

Aftab buliding, Ghalee Ave, Zanjan

City

Zanjan

Province

Zanjan

Postal code

7854329003

Phone

+98 24 3341 2597

Email

dr.b.nazemi@gmail.com

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

City

Zanjan

Province

Zanjan

Postal code

9876675432

Phone

+98 24 3315 6141

Email

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

Street address

Zanjan university of medical sciences, Mahdavi Blvd, Mahdavi Ave

City

Zanjan

Province

Zanjan

Postal code

7698654327

Phone

+98 24 3341 2597

Email

dr.b.nazemi@gmail.com

Person responsible for scientific 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

Street address

Zanjan university of medical sciences, Mahdavi Blvd, Mahdavi Ave

City

Zanjan

Province

Zanjan

Postal code

4513813657

Phone

+98 24 3341 2597

Fax**Email**

dr.b.nazemi@gmail.com

Person responsible for updating data

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

Street address

Zanjan university of medical sciences, Mahdavi Blvd,
Mahdavi Ave

City

Zanjan

Province

Zanjan

Postal code

4513813657

Phone

+98 24 3341 2597

Fax

Email

dr.b.nazemi@gmail.com

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

seyede solmaz taheeri: solmaz.taheeri.1990@gmail.com:

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