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Completed

Efficacy of the Use of Silver Diamine Fluoride and Sodium Fluoride Varnish for the Treatment of Caries in Children

ClinicalTrials.gov ID NCT05638217

Sponsor Universidad Mayor de San Simón

Information provided by Rodrigo Arce Cardozo, Universidad Mayor de San Simón (Responsible Party)

Last Update Posted 2023-11-18

Study Details Tab

Study Overview

Brief Summary

The goal of this observational study is to identify the efficacy of silver diamine fluoride 38% followed by sodium fluoride varnish 5% in a population with untreated dental caries age range 4 to 12 years old. The main questions to answer are

- Efficacy of treatment of active tooth decay with the treatment protocol of 38% silver diamine fluoride and 5% sodium fluoride varnish.
- Clinical evaluation of tooth decay treated with 38% silver diamine fluoride and 5% sodium fluoride varnish in quality of hardness, color change and caries progression.
- Explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with: i. Reduction of oral pain caused by the presence of carious lesions. ii. Improvement in gingival oral health. iii. Changes in general nutritional status through measurements of height, weight, hemoglobin levels and nutritional survey. The participants will be identified, charted (with nutritional surveys and parameters), as well as treated and compared in a six- and twelve-month period, where researchers will clinically identify the association between the use of this protocol and the efficacy of such, as well as other related nutritional aspects.

Official Title

Prospective Cohort Study: Efficacy of the Use of 38% Silver Diamine Fluoride and 5% Sodium Fluoride Varnish in Patients 4 to 12 Years for the Treatment of Caries and Its Association With Other Aspects of Relevance

Conditions

Dental Caries in Children

Intervention / Treatment

- Combination Product: Silver diamine fluoride 38% followed by Sodium fluoride varnish 5%

Other Study ID Numbers ⓘ

- DINV-CAV01-EC001

Study Start (Actual) ⓘ

2022-11-07

Primary Completion (Actual) ⓘ

2023-11-15

Study Completion (Actual) ⓘ

2023-11-15

Enrollment (Actual) ⓘ

199

Study Type ⓘ

Observational

Resource links provided by the National Library of Medicine

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>), related topics: [Tooth Decay](https://medlineplus.gov/toothdecay.html) (<https://medlineplus.gov/toothdecay.html>).

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>), available for: [Sodium fluoride](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Sodium+fluoride) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Sodium+fluoride>), [Fluorine](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Fluorine) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Fluorine>), [Fluoride](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Fluoride) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Fluoride>), [Listerine](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Listerine) (<https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Listerine>).

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>).

Contacts and Locations

This section provides the contact details for those conducting the study, and information on where this study is being conducted.

This study has 1 location

Bolivia

 **Cochabamba, Bolivia, 00000**
Bolivian Food Bank Foundation

[Click to view interactive map](#)

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies \(https://clinicaltrials.gov/study-basics/learn-about-studies\)](https://clinicaltrials.gov/study-basics/learn-about-studies).

Eligibility Criteria

Description

Inclusion Criteria:

- The patient must be able to receive all necessary treatments and may be followed up for additional treatments and/or record follow-ups at each time point and for the duration of the study.
- Children within the age range mentioned above.
- Require a completed informed consent form and completed nutritional survey record for anyone who will participate in the program.
- According to the evaluation of the dentist Caries grade I and grade II
- In the case of patients with disabilities, at least one parent or legal guardian must be present at all times during the study.

Exclusion Criteria:

- Patients who, after assessment, identify a pulp condition or abscess in any of the teeth, this affected piece will be excluded from receiving treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish (in these cases, the Patient Coordinator will refer to a dentist outside the study for their treatment)
- Patients with caries with grade III or grade IV
- Patients with a known allergy to any of the active ingredients (38% silver diamine fluoride and 5% sodium fluoride varnish)
- Patients who were unable to give their informed consent or complete the nutritional survey.
- Patients who cannot participate during the entire program (12 months).
- Patients with other oral treatments (Orthodontics).
- Patients who are not present with at least one parent or legal guardian at the time of treatment.

Study Population

This study will be carried out in the city of Cochabamba, Bolivia, specifically at the Bolivian Food Bank Foundation located on Calle Francisco Prada between Aurelio Melean and J. Arauco 1120, from November 2022 to November 2023. This is a prospective cohort with a single assignment group (children aged 4 to 12 years) where a sample of 100-150 patients will be evaluated before, during and after their treatment.

Ages Eligible for Study ⓘ

4 Years to 12 Years (Child)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

Sampling Method

Non-Probability Sample

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Observational Model ⓘ : Cohort

Time Perspective: Prospective

Groups and Interventions

Groups/Cohorts ⓘ	Intervention/Treatment ⓘ
<p>Patients of 4 to 12 years old eligible to received dental cavity treatment</p> <p>Patients of 4 to 12 years old that are eligible to received dental cavity treatment. The goal of this observational study is to identify the efficacy of silver diamine fluoride 38% followed by sodium fluoride varnish 5%, using "CaviGuard®" as delivery method, in a population with untreated dental caries age range 4 to 12 years old.</p>	<p>Combination Product: Silver diamine fluoride 38% followed by Sodium fluoride varnish 5%</p> <ul style="list-style-type: none"> • 1) Completely drying of the affected area 2) 10 microliters of silver diamine fluoride 38% (CaviGuard®) will be placed on the affected area 3) The affected area should be immediately covered with 20 microliters of fluoride varnish 5% (CaviGuard®) 4) Repeat steps 1-3 one or two more times for large caries at intervals of at least 2 days apart 5) Follow up evaluation of treatment success visits will be conducted at 6 and 12 months from the initial treatment. <p>NOTE: This is a single intervention using the device registered as Caviguard® to apply both products (Silver diamine fluoride 38% followed by Sodium fluoride varnish 5% (®)) in sequence.</p> <ul style="list-style-type: none"> • Other Names: <ul style="list-style-type: none"> ◦ CaviGuard®, Silver Diamine Fluoride (SDF)

What is the study measuring?

Primary Outcome Measures ⓘ

Outcome Measure	Measure Description	Time Frame
Ratio of arrested cavity lesions after treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish	The investigators will evaluate the efficacy of treatment of active cavity lesions arrested after using the treatment protocol with 38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist conducting an evaluation of multiple clinical findings including signs and symptoms of an active or arrested cavity. The clinical evaluation will be recorded in an odontograph for each patient.	6 months from initial treatment
Ratio of arrested cavity lesions after	The investigators will evaluate the efficacy of treatment of active cavity lesions after using the treatment protocol with	12 months from

treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish	38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist conducting an evaluation of multiple clinical findings including signs and symptoms of an active or arrested cavity. The clinical evaluation will be recorded in an odontograph for each patient.	treatment
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Secondary Outcome Measures 

Outcome Measure	Measure Description	Time Frame
Evaluate hardness	The investigators will evaluate the efficacy of treatment of active cavity lesions after using the treatment protocol with 38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist, conducting an evaluation of clinical finding that include hardness. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable hardness.	6 months from treatment
Evaluate color change	The investigators will evaluate the efficacy of treatment of active cavity lesions after using the treatment protocol with 38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist, conducting an evaluation of clinical finding that include color change. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable color change.	6 months from treatment
Evaluate cavity progression of cavity treated	The investigators will evaluate the efficacy of treatment of active cavity lesions after using the treatment protocol with 38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist, conducting an evaluation of clinical finding that include cavity progression. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable cavity progression.	6 months from treatment
Evaluation the reduction of oral pain caused by the presence of carious lesions.	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the reduction of oral pain caused by the presence of carious lesions. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable reduction of oral pain.	6 months from treatment
Evaluate Improvement in	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with	6 months from

gingival oral health.	the Improvement in gingival oral health. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable gingival oral health.	treatment
Evaluate changes in height and weight	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the patient nutritional status through measurements of height and weight that will be combined with height and weight for age in child grow standards from the world health organization.	6 months from treatment
Evaluate changes in hemoglobin levels	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the patient nutritional status through measurements of hemoglobin levels recorded as (g/dl).	6 months from treatment
Evaluate changes in a nutritional survey	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the patient nutritional status through a 59 question nutritional survey developed by the research team.	6 months from treatment
Evaluate hardness	The investigators will evaluate the efficacy of treatment of active cavity lesions after using the treatment protocol with 38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist, conducting an evaluation of clinical finding that include hardness. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable hardness.	12 months from initial treatment
Evaluate color change	The investigators will evaluate the efficacy of treatment of active cavity lesions after using the treatment protocol with 38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist, conducting an evaluation of clinical finding that include color change. The clinical evaluation will be recorded odontograph for each patient and include dichotomous variables (yes/no) for the variable color change.	12 months from initial treatment
Evaluate cavity progression of cavity treated	The investigators will evaluate the efficacy of treatment of active cavity lesions after using the treatment protocol with 38% silver diamine fluoride and 5% sodium fluoride varnish. This evaluation will be performed by a trained dentist, conducting an evaluation of clinical finding that include cavity progression. The clinical evaluation will be recorded	12 months from initial treatment

	odontograph for each patient and include dichotomous variables (yes/no) for the variable cavity progression.	
Evaluation of the reduction of oral pain caused by the presence of carious lesions	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the reduction of oral pain caused by the presence of carious lesions. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable reduction of oral pain.	12 months from initial treatment
Evaluate Improvement in gingival oral health.	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the Improvement in gingival oral health. The clinical evaluation will be recorded in an odontograph for each patient and include dichotomous variables (yes/no) for the variable gingival oral health.	12 months from initial treatment
Evaluate changes in height and weight	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the patient nutritional status through measurements of height and weight that will be combined with height and weight for age in child grow standards from the world health organization.	12 months from treatment
Evaluate changes in hemoglobin levels	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the patient nutritional status through measurements of hemoglobin levels recorded as (g/dl).	12 months from treatment
Evaluate changes in a nutritional survey	The investigators will explore the association of treatment with 38% silver diamine fluoride and 5% sodium fluoride varnish with the patient nutritional status through a 59 question nutritional survey developed by the research team.	12 months from treatment

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor

Universidad Mayor de San Simón

Collaborators

- Universidad Privada del Valle, Sede Cochabamba
- Industria Química Farmacéutica SIGMA CORP S.R.L. Cochabamba, Bolivia
- NODK LLC, Oregon, EE. UU.

- Food Bank Bolivia

Investigators ?

- Principal Investigator: Nathaly Campero Ferrufino, DDS, Private University of the Valley
- Principal Investigator: Ximena Claros Martinez, DDS, Private University of the Valley
- Principal Investigator: Edwin Guarayo Molina, DDS, Private University of the Valley
- Principal Investigator: Rodrigo k Arce Cardozo, MD, MPH,, Universidad Mayor de San Simon
- Principal Investigator: Steve Duffin, DDS, NODK LLC

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ?

2022-11-10

First Submitted that Met QC Criteria ?

2022-12-01

First Posted ?

2022-12-06

Study Record Updates

Last Update Submitted that met QC Criteria ?

2023-11-16

Last Update Posted ?

2023-11-18

Last Verified ?

2023-11

More Information

Terms related to this study

Keywords Provided by Rodrigo Arce Cardozo, Universidad Mayor de San Simón

Oral Health
Dental Caries
Silver Diamine Fluoride
Caries in Children

CaviGuard®

Additional Relevant MeSH Terms

Tooth Demineralization

Tooth Diseases

Stomatognathic Diseases

Dental Caries

Cariostatic Agents

Protective Agents

Physiological Effects of Drugs

Anti-Infective Agents, Local

Anti-Infective Agents

Listerine

Fluorides

Sodium Fluoride

Fluorides, Topical

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

No

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

No

Studies a U.S. FDA-Regulated Device Product

No

Helpful Links Provided by Rodrigo Arce Cardozo, Universidad Mayor de San Simón

[Description Intervention \(https://caviguard.com/\)](https://caviguard.com/)