# Dental remineralization with a silver nanoparticle compound

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>	
25/07/2024		Protocol	
Registration date	Overall study status	Statistical analysis plan	
19/08/2024	Completed	Results	
Last Edited	Condition category	[] Individual participant data	
18/08/2024	Oral Health	[] Record updated in last year	

# Plain English summary of protocol

Background and study aims

Dental caries (tooth decay) is the most frequent oral disease in children. Silver diamine fluoride can prevent caries with the adverse effect of tissue pigmentation. The main of the present study is to evaluate the effectiveness of a compound of silver nanoparticles with a fluoride varnish to mineralize dentine affected by tooth decay.

# Who can participate?

Healthy schoolchildren aged 6 to 9 years old with caries in primary molars (milk teeth)

#### What does the study involve?

Primary molars are distributed into two groups: Group A is treated with a compound based on silver nanoparticles and Group B with a silver diamine fluoride compound as a control treatment. All participants receive a clinical oral examination and radiographic diagnosis at the beginning of the study and the application of the treatments every 6 months for one and a half years.

# What are the possible benefits and risks of participating?

The children participating in the study are included in an oral health program for diagnosis and preventive treatments and receive a painless and easy treatment to stop their caries lesions. There are minimal possible risks because the treatments are safe and carried out under safety measures by experienced pediatric dentists. The secondary effect of pigmentation of the cavities treated with diamine fluoride silver could be observed.

#### Where is the study run from?

Reforma Multidisciplinary Clinic of the Faculty of Superior Studies of Zaragoza (Mexico)

When is the study starting and how long is it expected to run for? April 2021 to March 2024

Who is funding the study?

Universidad Nacional Autónoma de México (Mexico)

Who is the main contact?
Maria Lilia Adriana Juarez Lopez, marialiliajuarez\_0403@comunidad.unam.mx, lilia.
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# Contact information

# Type(s)

Public, Scientific, Principal investigator

#### Contact name

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

FESZ -CE/21-208-05

# Study information

#### Scientific Title

Effectiveness of remineralization with compound silver nanoparticles and fluoride varnish in caries lesions

# Study objectives

Silver nanoparticle compound is a conservative treatment to stop the progression of dental caries

# Ethics approval required

Ethics approval required

#### Ethics approval(s)

approved 29/07/2021, Research Committee of Faculty of High Studies of Zaragoza, Mexican National University (Campus 2 Batalla 5 de mayo S/N, Iztapalapa, 09230, Mexico; +52 (0) 5556230724; div.posgrado.investigacion@zaragoza.unam.mx), ref: FESZ -CE/21-208-05

# Study design

Non-randomized study

# Primary study design

Interventional

# Study type(s)

Treatment

# Health condition(s) or problem(s) studied

Dental caries

#### **Interventions**

Primary molars were distributed into two groups: Group A was treated with a compound based on silver nanoparticles and Group B with silver diamine fluoride compound as control treatment. Laser fluorescence was used for evaluation, with follow-up examinations at 15 days, 6 and 12 months. Also, a clinical examination for the detection of active or arrest caries lesions was performed at baseline and 12 months.

This study was conducted in a convenience sample of school children aged 6 to 9 years with at least two carious lesions in primary molars. The selected molars were assigned to each study group, taking care that both treatments were applied to one of the carious molars of the same patient.

# Intervention Type

Procedure/Surgery

# Primary outcome(s)

Remineralization measured for each caries lesion using the Diagnodent pen test (laser fluorescence) and data will be recorded at baseline and after each application: 15 days, 6 and 12 months

# Key secondary outcome(s))

The arrest of caries lesions measured by considering the texture and colour of the caries lesions by clinical inspection with the aid of a WHO probe to classify them as active or arrested lesions at baseline and 12 months

# Completion date

15/03/2024

# **Eligibility**

# Key inclusion criteria

- 1. Children with caries lesions
- 2. Children agree to participate in the study

# Participant type(s)

**Patient** 

# Healthy volunteers allowed

No

# Age group

Child

# Lower age limit

6 years

#### Upper age limit

9 years

#### Sex

Αll

# Total final enrolment

40

# Key exclusion criteria

- 1. Children with general disease
- 2. Molars with non-reversible pulpitis, abscesses

### Date of first enrolment

26/08/2022

#### Date of final enrolment

30/10/2022

# Locations

#### Countries of recruitment

Mexico

# Study participating centre Lazaro Cardenas School

Norte 10 Col. Reforma C.P. 57840 Ciudad Nezahualcóyotl Estado de México Mexico City Mexico 09230

# Sponsor information

# Organisation

Universidad Nacional Autónoma de México

#### ROR

https://ror.org/01tmp8f25

# Funder(s)

#### Funder type

Government

#### **Funder Name**

Dirección General de Asuntos del Personal Académico, Universidad Nacional Autónoma de México

## Alternative Name(s)

General Directorate of Academic Personal Affairs, General Direction of Academic Staff Affairs, UNAM - Dirección General Asuntos del Personal, Dirección General de Asuntos del Personal Académico, Dirección General de Asuntos del Personal Académico (DGAPA) de la Universidad Nacional Autónoma de México (UNAM), DGAPA, UNAM, DGAPA

# Funding Body Type

Government organisation

# Funding Body Subtype

Universities (academic only)

#### Location

Mexico

# **Results and Publications**

## Individual participant data (IPD) sharing plan

The datasets generated during the current study will be stored in a non-public repository of the Mexican National University

# IPD sharing plan summary

Stored in non-publicly available repository, Published as a supplement to the results publication

# Study outputs

Output type **Details** Date created Date added Peer reviewed? Patient-facing?