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Dental remineralization with a silver nanoparticle compound

Submission date	Recruitment status	[_] Prospectively registered
25/07/2024	No longer recruiting	[_] 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	[X] 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?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

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 measure
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

Secondary outcome measures

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

Overall study start date
24/04/2021

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

Age group
Child

Lower age limit
6 Years

Upper age limit
9 Years

Sex
Both

Target number of participants
40

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

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Sponsor type
University/education

Website
https://www.zaragoza.unam.mx/

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)
Dirección General de Asuntos del Personal Académico, General Direction of Academic Staff Affairs, UNAM - Dirección General Asuntos del Personal, General Directorate of Academic Personal Affairs, DGAPA, UNAM, DGAPA

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Mexico

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
30/09/2024

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