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THE EFFECTIVENESS OF A SUSTAINABLE SILVER NANOPARTICLE PRODUCT IN STOPPING CARIES IN CHILDREN

A EFICÁCIA DE UM PRODUTO SUSTENTÁVEL DE NANOPARTÍCULAS DE PRATA NA PREVENÇÃO DE CÁRIES EM CRIANÇAS

LA EFICACIA DE UN PRODUCTO SOSTENIBLE DE NANOPARTÍCULAS DE PLATA PARA DETENER LAS CARIES EN NIÑOS

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DOI: 10.54899/dcs.v22i82.3092
Recibido: 16/07/2025 | Aceptado: 21/07/2025 | Publicación en línea: 15/09/2025.

ABSTRACT

Objective: This study aims to evaluate caries arrest properties of a liquid solution containing a natural colloidal mineral compound with 40 ppm pure silver nanoparticles (AgNP) as a mouthwash in school-age children. This product is available in Brazil, the United States, Europe, Asia, and Oceania for its claimed germicidal action against pathogenic organisms, including gastrointestinal problems, skin wounds, and respiratory conditions; however, it is not for treating dental infections. Method: This randomized, double-masked clinical trial was conducted in a public school in the city of Recife, Brazil. The sample consisted of 104 children aged 6 to 9 years of both sexes. The chosen product was Almacura® brand Colloidal Silver. A group of calibrated dentists from the University of Pernambuco performed a dental inspection and recorded the dmft

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and DMFT index of the children. After the baseline evaluation, the children were randomly assigned into two groups. In Group 1 (intervention), children rinsed their teeth with the experimental solution. Children in Group 2 (control) brushed their teeth only with fluoridated toothpaste. Children had supplies of toothbrushes and fluoridated toothpaste. The first follow-up exam, assessing caries progress, was at a three-month interval. Arrested caries were those whose activity ceased within three months. Result: This study indicated that the AgNP solution mouthwash arrested carious lesions on its own within three months. The analytical statistics revealed a significant association between caries arrest and the use of the product ($P < 0.05$). However, the efficacy indicated an NNT of 6, meaning that six children need to be treated to prevent caries in one child. Conclusion: An AgNP product already marketed in several countries may serve as a coadjuvant method to prevent dental decay in children, to be used in conjunction with traditional methods, thereby increasing their effectiveness in combating dental disease. The product is low-cost and easy to apply.

Keywords: Preventive Dentistry. Silver. Dental Caries. Children.

RESUMO

Objetivo: Este estudo visa avaliar as propriedades de parada de cárie de uma solução líquida contendo um composto mineral coloidal natural com 40 ppm de nanopartículas de prata pura (AgNP) como enxaguante bucal em crianças em idade escolar. Este produto está disponível no Brasil, Estados Unidos, Europa, Ásia e Oceania por sua suposta ação germicida contra organismos patogênicos, incluindo problemas gastrointestinais, feridas de pele e condições respiratórias; no entanto, não é para tratar infecções dentárias. Método: Este ensaio clínico randomizado, duplo-cego, foi conduzido em uma escola pública na cidade de Recife, Brasil. A amostra foi composta por 104 crianças de 6 a 9 anos de ambos os sexos. O produto escolhido foi a Prata Coloidal da marca Almacura®. Um grupo de dentistas calibrados da Universidade de Pernambuco realizou uma inspeção odontológica e registrou o ceo-d e o índice CPO-D das crianças. Após a avaliação inicial, as crianças foram aleatoriamente divididas em dois grupos. No Grupo 1 (intervenção), as crianças enxaguaram os dentes com a solução experimental. As crianças do Grupo 2 (controle) escovaram os dentes apenas com creme dental fluoretado. As crianças tinham suprimentos de escovas de dente e creme dental fluoretado. O primeiro exame de acompanhamento, avaliando o progresso da cárie, foi em um intervalo de três meses. Cáries paradas foram aquelas cuja atividade cessou dentro de três meses. Resultado: Este estudo indicou que o enxaguante bucal com solução AgNP paralisou as lesões de cárie por si só dentro de três meses. A estatística analítica revelou uma associação significativa entre a parada da cárie e o uso do produto ($P < 0,05$). No entanto, a eficácia indicou um NNT de 6, o que significa que seis crianças precisam ser tratadas para prevenir a cárie em uma criança. Conclusão: Um produto AgNP já comercializado em vários países pode servir como um método coadjuvante para prevenir a cárie dentária em crianças, para ser usado em conjunto com métodos tradicionais, aumentando assim sua eficácia no combate à doença dentária. O produto é de baixo custo e fácil aplicação.

Palavras-chave: Odontologia Preventiva. Prata. Cárie Dentária. Crianças.

RESUMEN

Objetivo: Este estudio tiene como objetivo evaluar las propiedades de detención de caries de una solución líquida que contiene un compuesto mineral coloidal natural con 40 ppm de

nanopartículas de plata pura (AgNP) como enjuague bucal en niños en edad escolar. Este producto está disponible en Brasil, Estados Unidos, Europa, Asia y Oceanía por su supuesta acción germicida contra organismos patógenos, incluyendo problemas gastrointestinales, heridas en la piel y afecciones respiratorias; sin embargo, no está destinado al tratamiento de infecciones dentales. Método: Este ensayo clínico aleatorizado, doble ciego, se llevó a cabo en una escuela pública en la ciudad de Recife, Brasil. La muestra consistió en 104 niños de 6 a 9 años de ambos os sexos. El producto elegido fue Plata Coloidal marca Almacura®. Un grupo de dentistas calibrados de la Universidad de Pernambuco realizó una inspección dental y registró el índice cao y el índice CPOD de los niños. Después de la evaluación inicial, los niños fueron asignados aleatoriamente a dos grupos. En el Grupo 1 (intervención), los niños se enjuagaron los dientes con la solución experimental. Los niños del Grupo 2 (control) se cepillaron los dientes solo con pasta dental fluorada. Los niños tenían suministros de cepillos de dientes y pasta dental fluorada. El primer examen de seguimiento, que evaluó el progreso de la caries, se realizó en un intervalo de tres meses. Las caries detenidas fueron aquellas cuya actividad cesó en un plazo de tres meses. Resultado: Este estudio indicó que el enjuague bucal con solución de AgNP detuvo las lesiones cariosas por sí solo en un plazo de tres meses. Las estadísticas analíticas revelaron una asociación significativa entre la detención de la caries y el uso del producto ($P < 0,05$). Sin embargo, la eficacia indicó un NNT de 6, lo que significa que se necesitan tratar seis niños para prevenir la caries en un niño. Conclusión: Un producto de AgNP ya comercializado en varios países puede servir como un método coadyuvante para prevenir la caries dental en niños, para ser utilizado junto con los métodos tradicionales, aumentando así su eficacia en el combate de la enfermedad dental. El producto es de bajo costo y fácil de aplicar.

Palabras clave: Odontología Preventiva. Plata. Caries Dental. Niños.

INTRODUCTION

According to a 2022 report by the World Health Organization (WHO), dental caries is a public health problem worldwide, with approximately 2 billion cases in permanent teeth and 510 million in deciduous teeth, causing chronic pain, infections, and even psychosocial changes, affecting the quality of life of children and their families (1,2).

Dental caries affect more vulnerable and disadvantaged populations, especially children, highlighting health inequality. Poor oral health can be associated with school absenteeism and lower academic performance in children, resulting in lower grades (3).

Historically, silver compounds have been used for over 100 years as antimicrobial agents to treat various infections, including halting the progression of dental caries. This preparation was later combined with fluoride, resulting in Silver Diamino Fluoride (SDF), which has a high

concentration of silver, approximately 280,000 ppm, varying according to the manufacturer, and is very popular in Japan, China, Argentina, and Australia. It has proven to be an effective therapeutic agent for stopping dental caries efficiently. However, due to the formation of molecular silver, the compounds stain the tooth surface and can cause ulcerations in the mucosa (4,5).

To overcome the disadvantages of SDF, more recently, Nano Silver Fluoride (NSF), a colloid of silver nanoparticles (AgNPs) with much lower concentrations of silver, at 400 ppm and 600 ppm, is non-toxic and does not stain tooth enamel black (6,7). Arnaud *et al*. (7) reported that NSF-based compounds can increase access to dental care for poor children due to their low cost and simple topical application on decayed tooth surfaces.

AgNP-based solution products are widely available in the international market, particularly in several countries across the Americas, Europe, Asia, and Oceania, as cosmetics that utilize AgNP technology for their antimicrobial, antiseptic, and anti-inflammatory properties (8). In Brazil, AgNP solutions have been available on the market under various brands for over 30 years to treat gastrointestinal problems, skin wounds, and respiratory infections, as well as to serve as deodorants, soaps, toothpaste, and mouthwashes, which claim to freshen breath and maintain mouth health (9,10).

Among the brands available in Brazil, Almacura®, a 40ppm Colloidal Silver solution, was chosen for this randomized controlled study due to its lower cost compared to other available products. It is a liquid solution of a natural colloidal mineral compound containing pure AgNP (silver1000), deionized water obtained through a low-voltage silver electrolysis reactor and has a crystal clear color. It is marketed as having a highly germicidal action against pathogenic organisms and is safe for human use (11). However, there is still no scientific evidence of its action against dental pathogens or its ability to stop the progression of caries lesions.

Therefore, this study aimed to evaluate caries-arresting properties of Almacura 40ppm as a mouthwash in school-age children to establish an effective, safe, and self-sustainable protocol for treating this disease.

MATERIALS AND METHODS

This study was a randomized, double-masked clinical trial conducted in a public school in the city of Recife, Brazil, following the CONSORT (Consolidated Standards of Reporting

Trials) guidelines. The study population consisted of children aged 6 to 9 years of both sexes. This study targeted children aged 6 to 7 years because, at this age, they have mixed dentition with newly erupted first permanent molars and are capable of avoiding swallowing the solution.

The sample size calculation was based on the difference in proportion reported in a previous study (7), with a significance level of 5%, a test power of 95%, and a success rate in the application of the NSF of 67%, resulting in a sample size of 104 children. This study included caries-free children or those presenting dental cavities in enamel and dentin. The prevalence of caries was recorded according to the dmft/DMFT index (13,14). Non-cooperative children and those with health conditions that prevented them from participating in the trial were excluded from the sample.

The chosen silver nano solution was AlmacuraThis study was a randomized, double-masked clinical trial conducted in a public school in the city of Recife, Brazil, following the CONSORT (Consolidated Standards of Reporting Trials) guidelines. The study population consisted of children aged 6 to 9 years of both sexes. The choice of age group was justified by the presence of mixed dentition with newly erupted first permanent molars and the capability of older children not to swallow the solution.

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The chosen silver nano solution was Almacura Colloidal Silver, which the manufacturer describes as a natural mineral compound formed by pure AgNP (Silver 1000), unalloyed with other metals, suspended in pure deionized water. It was obtained through a low-voltage electrolysis reactor using a slow production process. The Chemical department of the University Federal de Pernambuco carried out the tests for characterization of the solution by UV-Visible absorption spectroscopy (UV-Vis) and an Ocean Optics DH-2000 spectrophotometer with deuterium and tungsten lamps and a 10 mm wide rectangular quartz cuvette. The Scanning Transmission Electron Microscopy (STEM evaluated the shape of the nanoparticles.

Two calibrated dentists performed data collection. The Interclass Correlation Coefficient was obtained by the Kappa test, which was 0.81. The dentist who did not participate in the initial examination performed the follow-up evaluation at the three-month interval. The examiners recorded decayed, missing, and filled teeth in the deciduous and permanent dentition on a standardized form. The examination was conducted in a school environment, utilizing visual and tactile assessments with a wooden spatula, a WHO probe, and gauze to control saliva following the biosafety protocols.

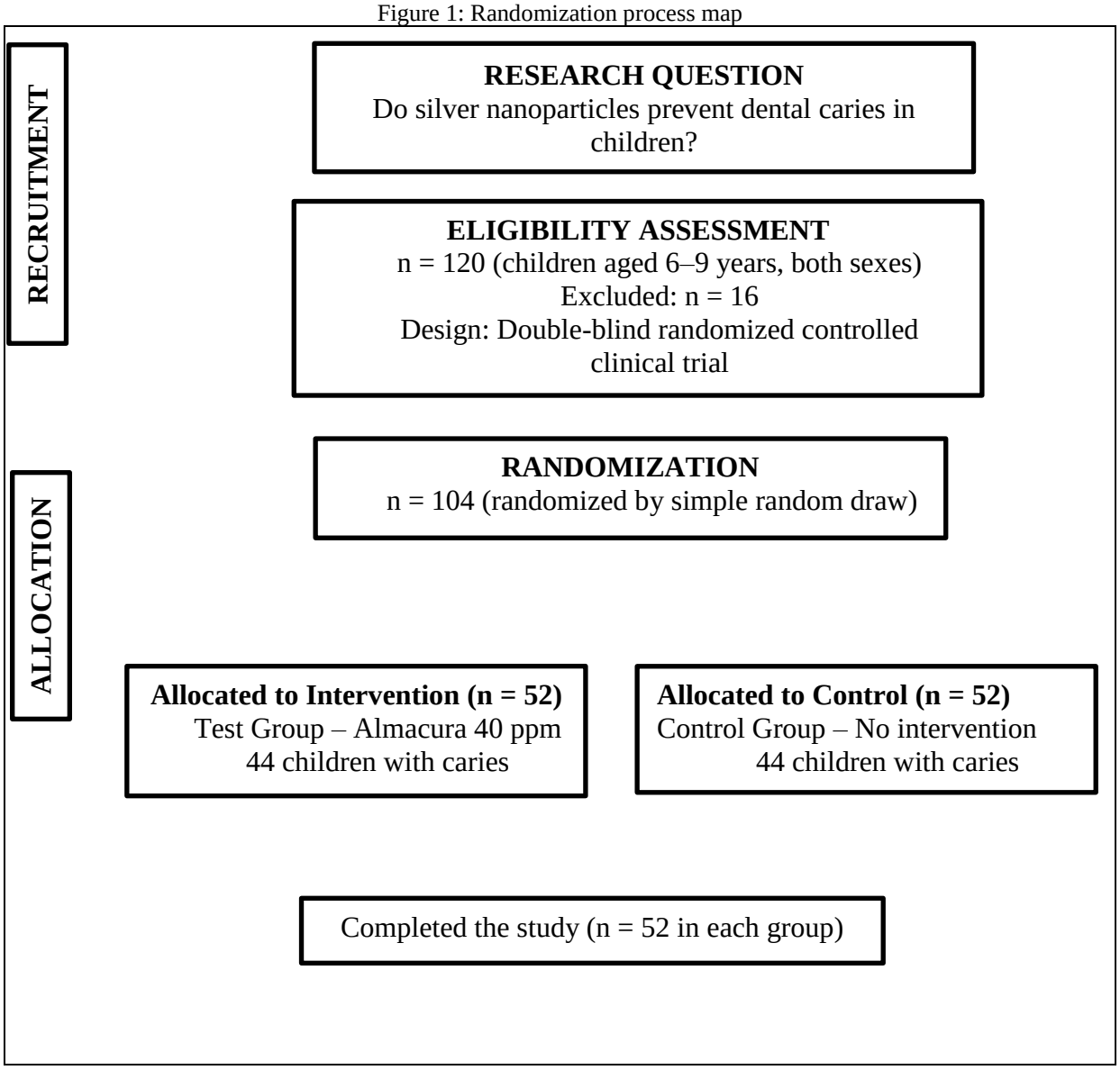
After initial assessment and recording of dmft and DMF the children were distributed, through simple randomization performed by the Epi Info program, into two groups: Group 1 (Intervention) - the children rinsed their mouths with 20 ml of the experimental solution (Almacura® Colloidal Silver 40 ppm) for 1 minute and took home toothbrushes and fluoridated toothpaste; in Group 2 (control), the children brushed their teeth only with fluoridated toothpaste.

All children who participated in the study underwent follow-up examinations at 3-month intervals to assess caries arrest or increase in caries. Regarding the outcome, the number of paralyzed caries was considered those whose activities ceased within 3 months—children with active caries lesions within this time were referred for clinical restorative treatment. Caroius lesions were those observed in any tooth previously diagnosed as healthy or in the same tooth on another site (figure 1).

Statistical calculations used the SPSS 20.0 statistical software. Data were analyzed by descriptive method using absolute and relative measures, mean, standard deviation, and median. An abnormal distribution pattern of data was identified using the Kolmogorov-Smirnov test ($p<0.001$). Data were analyzed using the Mann-Whitney test and paired with the Wilcoxon test to verify statistically significant differences at the 5% level. The efficiency of the solution to arrest dental decay was measured by Relative Risk (RR): Odds Ratio (OR); Absolute Risk Reduction (ARR): Difference between the risk in unexposed and exposed individuals and Relative Risk Reduction (RRR), percentage of risk reduction in exposed individuals about the risk in unexposed individuals and NNT, number needed to treat.

This research followed Resolution 466/2012 of the National Health Council (CNS) and was approved by the Ethics and Research Committee of the Hematology and Hemotherapy Foundation of Pernambuco (HEMOPE) under opinion number 4.346.698. Only children whose guardians signed the Free and Informed Consent Form (FICF) and the Free and Informed Assent Form (FICF) took part in this study.

Figure 1: Randomization process map



Source: Prepared by the author

Figure 2: Income statement

ANALYSIS

ANALYZED (n = 52)
Excluded from analysis: n = 0
Had caries: 30 (57.7%)
Cavity-free: 22 (42.3%)
Improved: 14

ANALYZED (n = 52)
Excluded from analysis: n = 0
Had caries: 39 (75.0%)
Cavity-free: 13 (25.0%)
Improved: 7

RESULTS

SAMPLE CHARACTERISTICS

- Total number of participants (n = 104)
- Overall mean number of decayed teeth:
  - *1st assessment: 2.49 ± 2.48*
  - *2nd assessment: 2.34 ± 2.30*
- **Age distribution:**
  - ≤7 years: 46 participants
  - ≥8 years: 58 participants
  - *No statistically significant differences between age groups*
- Sex distribution:
  - **Female: 41 participants**
  - **Male: 63 participants**

2X2 CONTINGENCY TABLE

Group	Cavity free	Cavity free	Total
AgNP + Fluoridated Toothpaste	8 (a)	22 (b)	52
Fluoridated Toothpaste	6 (c)	13 (d)	52

OR = (a x d) / (b x c) = (30 x 13) / (22 x 39)

CALCULATION OF THE ODDS RATIO

Odds grupo teste: 30/22 = 1,36
Odds grupo controle: 39/13 = 3,00
OR = 390 / 858 = 0,45
OR = 0,45 (IC 95%: 0,23 – 0,89)

The OR = 0.45 indicates that the intervention group has a 55% lower chance (1 - 0.45 = 0.55) of having cavities compared to the control group.

EFFECT MEASURES

- Relative Risk (RR): 0.5910
- Relative Risk Reduction (RRR): 40,9%
- Absolute Risk Reduction (ARR): 17%
- Number Needed to Treat (NNT): 6

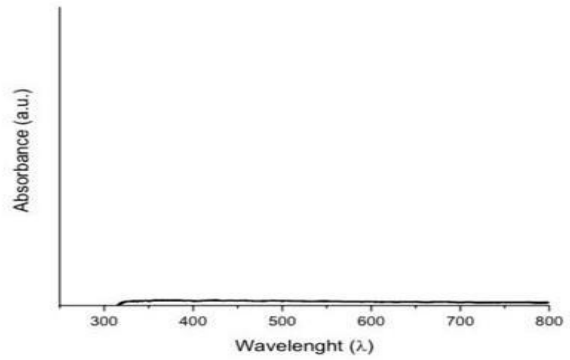
The treatment reduced the relative risk of developing cavities by 40.9% compared to the control group.

Source: Prepared by the author

RESULTS

The Almacura® 40ppm solution underwent spectroscopy for characterization of the chemical components of the solution and did not present a high absorption peak for silver nanoparticles, as shown in Graph 1. The result indicates a low concentration of nanoparticles in the sample. Most of the silver found in the sample were Ag+ ions.

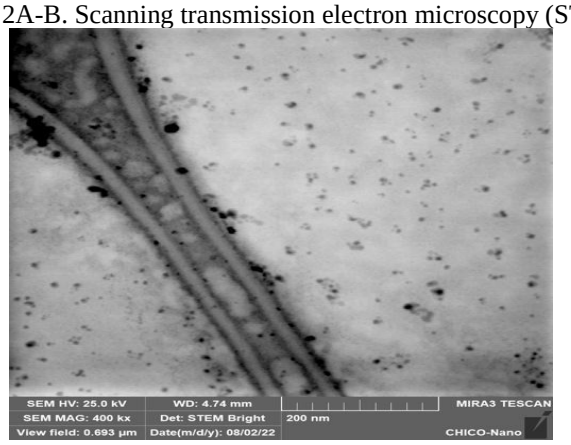
Graph 1. UV-Visible absorption spectroscopy



Source: Prepared by the author

Scanning transmission electron microscopy revealed the presence of nanometric-sized spherical particles in some regions of the grid (a carbon-coated copper grid) on which a drop of the sample was deposited (Figures 2A-B). This result corroborates the hypothesis that there are nanoparticles in the sample, but in low concentration, while most of the silver was dissolved in its ionic form.

Figure 2A-B. Scanning transmission electron microscopy (STEM)



Source: Prepared by the author

Among the final sample of 104 individuals, it was possible to identify an average of 2.49 (±2.485) decayed teeth per child in the 1st evaluation; and 2.34 (±2.297) in the follow-up evaluation. When comparing the control and test groups, it was possible to verify a significantly lower mean number of decayed teeth in the children who received. the mouthwash ($p<0.001$). Regarding sex and age, there was no statistically significant difference between the groups at either of the two evaluation times ($p>0.05$) (Table 1).

Table 1. Comparative distribution of the number of decayed teeth between groups (n = 104). Brazil, 2024

	1st Assessment				
	N	**Average**	**DP**	**Median**	**p-value***
Group					
Control	52	3.21	2.569	3.00	0.002
Test	52	1.77	2.193	1.00	
Sex					
Feminine	41	2.68	2.573	2.00	0.446
Masculine	63	2.37	2.438	2.00	
Age (in years)					
≤7	46	2.91	2.674	2.00	0.156
≥8	58	2.16	2.293	1.50	
Total	**104**	**2.49**	**2.485**	**2.00**	
	2nd Assessment				
	N	**Average**	**DP**	**Median**	**p-value***
Group					
Control	52	3.29	2.508	3.00	<0.001
Test	52	1.38	1.586	1.00	
Sex					
Feminine	41	2.46	2.430	2.00	0.631
Masculine	63	2.25	2.21	2.00	
Age (in years)					
≤7	46	2.78	2.520	2.50	0.134
≥8	58	1.98	2.056	1.00	
Total	**104**	**2.34**	**2.297**	**2.00**	

SD = Standard Deviation. *Trought the Mann-Whitney test.
Source: Prepared by the author

By analyzing the number of decayed teeth in the intervention group, it was possible to observe a statistically significant reduction in caries between the 1st and 2nd evaluation of the sample ($p = 0.007$), as presented in table 2.

Table 2. Paired analysis of the number of decayed teeth at the different moments of evaluation in the intervention group (n = 52). Brazil, 2024

	Number of decayed teeth				
	N	**Average**	**DP**	**Median**	**p-value****
Test group					
1st evaluation	52	1.77	2.193	1.00	0.007
2nd evaluation		1.38	1.586	1.00	

SD = standard deviation. **Throught Wilcoxon test.
Source: prepared by the author.

Table 3: Baseline Sample Characteristics

Characteriscic	**Total sample (n=104)**	**Statistical significance**
Total participants	104	-
Decayed teeth (1st assessment)	2.49 ± 2.48	-
Decayed teeth (2st assessment)	2.34 ± 2.29	-
Ange distribution		
≤ 7 years	46 (44.2%)	No statistical difference
≥ 8 years	58 (55.8)	Between ages
Sex distribution		
Female	41 (39.4%)	No statistical difference
male	63 (60.3%)	Between sexes

Source: Prepared by the author

Table 4: Group Allocation and Baseline Caries Status

Group	**Allocated (n)**	**Completed study (n)**	**Children with caris at baseline**
Test group (Almacura 40ppm)	52	52	44
Control group	52	52	46
Total	104	104	90

Source: Prepared by the author

Table 5: Almacura 40ppm Solution Characteristics

Analysis method	**Finding**	**Description**
Uv-visible spectroscopy	Low concentration of silver nanoparticles	Predominance of Ag + ions
Transmission electron microscopy	Nanometric spherical particles	Confirms presence of nanoparticles in low concentration

Source: Prepared by the author

Table 6: Clinical Outcomes by Group

Outcome	**Test group (n=52)**	**Control group (n=52)**
Had caries	30 (57.7%)	39 (75.0%)
Did not have caries	22 (42.3%)	13 (25.0%)
Improved	14	7

Source: Prepared by the author

Table 7: Measures of Treatment Effect

Statistical measure	**Value**	**outcomes**
Relative risk (RR)	0,5910	Treated individuals are 0.591 times less likely to have caries progression
Relative risk reduction (RRR)	0,409	40.9% reduction in relative risk
Absolute risk reduction	0,17	17% absolute reduction in caries risk
Number needed to treat (NNT)	6	6 children need treatment to prevent 1 case of caries

Source: Prepared by the author

DISCUSSION

Colloidal silver has been used worldwide for many years, mainly in the United States, oceania, and asia. It claims to be a therapeutic aid against pathogens in the human body. The solution tested in this study for mouth rinse was almacura® colloidal silver, 40ppm, available on the market, described by the manufacturer as a natural mineral compound formed by pure agnp (silver 1000), unalloyed with other metals, suspended in pure deionized water, obtained through a very low voltage electrolysis reactor through a slow production process.

Previous clinical trials tested the efficacy of silver products at various concentrations to halt caries (24-30, 32). Those products include fluoride and chitosan in their formulation, which may be active on their own against the progression of dental decay. Almacura® 40ppm agnp does not contain other elements in its formulation, which may indicate that silver nanoparticles alone can arrest dental caries.

Given that the size of the particles is inversely proportional to their antibacterial activity, where silver nanoparticles 35 ± 10 nm proved to be more effective in arresting dental caries than chlorhexidine and silver diamine fluoride (sdf). At higher concentrations, silver nanoparticles can agglomerate and increase in size, thereby compromising their cytotoxic capacity since nanoparticles larger than 50 nm cannot penetrate the dentine tubules to prevent the penetration of various pathogens (32). The present study tested a nanosilver product at a low concentration, and the results indicated significant differences when compared to the control group.

Results of this study indicated that, in addition to the reduction of new carious lesions, 14 children in the treated group (26.9% of the participants) showed a halt in pre-existing lesions, compared to 7 children in the control group (13.5%). This difference suggests that it is effective in preventing the progress of new lesions but may also have a therapeutic effect on initial carious lesions, contributing to the natural mechanisms of tooth remineralization.

The efficacy of almacura® 40ppm therapy in preventing caries progression may be related to multiple factors. This approach generally works by favoring the oral environment through the remineralization of dental tissues, modulation of the cariogenic microbiota, and strengthening of the host's natural defense mechanisms.

The 40.9% relative risk reduction indicates that the product is effective in halting dental decay; however, at a low rate, it may suggest that it may be used in conjunction with other traditional methods of caries prevention to enhance their effectiveness. The nnt of 6 indicates that six children must be treated to benefit one child, which is not the most effective scenario for making a significant impact in reducing caries when applied on its own.

The tested product can be combined with existing preventive methods, such as water fluoridation programs, professional fluoride application methods, and oral health education.

The complementary nature of this intervention enables its integration into existing therapeutic protocols without replacing the currently recommended evidence-based practices but rather enhancing them.

Although the inferential statistical results indicated an association between caries arrest and the use of the mouth rinse with the tested solution, the therapeutic measures revealed a 68% reduction in the relative risk of developing new caries lesions, demonstrating a low preventive impact of the intervention.

The relative risk reduction(rrr) of 40.9% confirms that treatment with almacura 40ppm reduces a tiny proportion of dental decay. It was also observed that the relative risk (rr) was 0.5910, with those treated being 0.591 less likely to present caries progression.

In absolute terms, the absolute risk reduction (arr) was 17%, representing the direct difference between the caries incidence rates observed in the two groups, which is low concerning the potential to prevent the progression of dental decay in children.

The number needed to treat (nnt) was 6, indicating that for every six children treated with almacura 40ppm, one additional carious lesion will be prevented, which is not the best scenario expected from a therapeutic method to halt caries. Therefore, more studies on innovative approaches for effectively arresting caries are still necessary to provide scientific evidence for using the new products as real medication

This study demonstrated promising results regarding the efficacy of therapy with almacura® 40ppm as a complement to conventional preventive treatment of dental caries in children. The product may serve as a complementary method to the already established

therapeutic protocols without replacing the currently recommended evidence-based practices but rather enhancing them.

CONCLUSION

This study indicated that the 40 ppm AgNP solution, Colloidal Silver 40 ppm, Almacura®, prevented the progression of dental caries in children; however, its efficacy is limited, and its use is recommended as an additional aid to other evidence-based methods used to arrest caries in children.

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APPENDIX

APPENDIX A – FREE AND INFORMED CONSENT FORM (FICF)

FREE AND INFORMED CONSENT FORM

(Prepared in accordance with Resolution 466/2012-CNS/CONEP)

Your child is being invited to participate in the study "Innovative Technique for Applying a Sustainable Product to Stop Cavities in Children," led by researcher Aronita Rosenblatt and her research team: Mônica Vilela Heimer, Débora Heloísa Silva de Brito, Thaysa Gomes Ferreira Tenório dos Santos, and Mabel Cristina Paiva. The main objective is to diagnose cavities and analyze the effectiveness of products to prevent and stop cavities.

If you wish for your child to participate in this study, dental exams will be performed and toothbrush and toothpaste kits will be donated at no cost to you. The exam involves observing the mouth using all the necessary techniques, safety, and hygiene, in accordance with the standards of the World Health Organization and the Ministry of Health. The toothpastes and solutions do not contain toxic substances or substances prohibited by ANVISA (National Health Regulatory Agency). Individual data will not be disclosed under any circumstances, but the research results will greatly contribute to better understanding the changes we are investigating and preventing oral diseases.

Regarding risks and discomfort, there is the potential discomfort to the participant during the clinical exam. Regarding mouthwashes, there are no studies in the literature on the risk of poisoning from swallowing the product at the concentration used in the research. As a protective measure for the participant, the clinical exam will be performed carefully and cautiously to avoid discomfort, as without this type of touch, it will not be possible to detect the problem or direct the patient appropriately. If parents/guardians feel that their children will be uncomfortable or embarrassed during any of the exams in question, they have the right to withdraw their participation. The expected benefits of this research are a reduction in cariogenic microorganisms in the oral cavity, stopping and preventing caries lesions. If we diagnose an active caries lesion that is not stopped within 30 days of using the products, we will inform you of the need for clinical treatment as soon as possible.

We clarify that we will maintain all data that identifies the research participant anonymously and under absolute confidentiality, during and after the end of the study, using only data inherent to

the study's development for dissemination. This data will be archived under the responsibility of the principal investigator. We also inform you that after the end of the research, all media that could identify you, such as videos, photos, recordings, etc., will be destroyed, leaving nothing that could compromise the anonymity of your participation now or in the future.

The child's guardian and the participating child will have the following rights: the guarantee of clarification and answers to any questions; The freedom to abandon the research at any time without harm to themselves or their treatment; the guarantee of privacy of their identity and confidentiality of their information; and the guarantee that if any harm occurs to the participant (or their guardian), the losses will be assumed by the researchers or the responsible institution, including medical and hospital follow-up. Any additional expenses will be covered by the researcher. If you have any questions or clarifications, you should contact the researchers through the following contacts:

Dr. Aronita Rosenblatt (81) 9 7110-0013 / Dr. Débora Heloísa Silva de Brito - (81) 9 9948-9669 / Dr. Thaysa Gomes Ferreira Tenório dos Santos – (81) 9 9530-0718 / Dr. Monica Vilela Heimer (81) 9 9969-1160 / Dr. Mabel Cristina Paiva M. Silva (81) 9 8779-5017. All with professional address at: Av. Gov. Agamenon Magalhães - Santo Amaro, Recife - PE, 50100-010. If your questions are not resolved by the researchers or your rights are denied, please contact the Human Research Ethics Committee, CEP: Av. Agamenon Magalhães, S/N, Santo Amaro, Recife-PE, or by phone: (81) 3183-3657 or by email: Comitê.etica@upe.gov.br.

We request your understanding and cooperation by authorizing participation in the examination and intervention in the box below.

I, _____,

guardian of the minor _____, after having received all clarifications and being aware of his/her rights, agree to allow him/her to participate in this research, and I also authorize the disclosure and publication of all information provided by him/her, except for personal data, in scientific publications and events. I hereby sign this agreement, together with the researcher, in two copies of equal content, with one copy remaining in my possession and the other in the possession of the researcher(s).

Place: _____ Date: ___/___/___

Signature of the minor's guardian

Signature of the principal researcher

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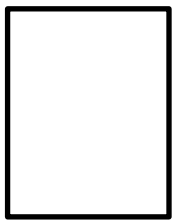

APPENDIX B - FREE AND INFORMED CONSENT FORM (TALE)

FREE AND INFORMED ASSENT FORM

(Prepared in accordance with Resolution 466/2012-CNS/CONEP)

You are being invited to participate in the study "Innovative Technique for Applying a Sustainable Product to Stop Cavities in Children," led by researcher Aronita Rosenblatt and her research team: Mônica Vilela Heimer, Débora Heloísa Silva de Brito, Thaysa Gomes Ferreira Tenório dos Santos, and Mabel Cristina Paiva. The main objective is to diagnose cavities and analyze the effectiveness of products to prevent and stop cavities.

If you wish to participate in this study, dental exams will be performed and toothbrush and toothpaste kits will be donated at no cost to you. The exam consists of an oral examination using all the necessary techniques, safety, and hygiene, in accordance with the standards of the World Health Organization and the Ministry of Health. The toothpastes and solutions do not contain toxic substances or substances prohibited by ANVISA. Individual data will not be disclosed under any circumstances, but the results of the study will greatly contribute to better understanding the changes we are investigating and preventing oral diseases. Regarding risks and discomfort, there is the potential discomfort to the participant during the clinical examination. Regarding mouthwashes, there are no studies in the literature on the risk of poisoning from swallowing the product at the concentration used in the study. As a protective measure for the participant, the clinical examination will be performed carefully and cautiously to avoid discomfort, as without this type of touch, it will not be possible to detect the problem or address it appropriately. If you do not wish to participate, there will be no harm to you.

The expected benefits of this study are a reduction in cariogenic microorganisms in the oral cavity, stopping and preventing caries lesions. If we diagnose an active caries lesion that is not stopped within 30 days of using the products, we will inform the need for clinical treatment as soon as possible.

We clarify that we will maintain anonymity and absolute confidentiality, during and after the study, all data that identifies the research participant, using only data inherent to the study's development for dissemination. This data will be archived under the responsibility of the principal investigator. We also inform you that after the research is completed, any and all media that could potentially identify you, such as videos, photos, recordings, etc., will be destroyed, leaving

nothing that could compromise the anonymity of your participation now or in the future.

Participants will have the following rights: the guarantee of clarification and answers to any questions; the freedom to abandon the research at any time without harm to themselves or their treatment; the guarantee of privacy regarding their identity and the confidentiality of their information; and the guarantee that if any harm occurs to the participant (or their guardian), the losses will be borne by the researchers or the responsible institution, including medical and hospital care. Any additional expenses will be borne by the researcher. If you have any questions or require clarification, please contact the researchers using the following contact information:

Dr. Aronita Rosenblatt (81) 9 7110-0013 / Dr. Débora Heloísa Silva de Brito - (81) 9 9948-9669 /

Dr. Thaysa Gomes Ferreira Tenório dos Santos – (81) 9 9530-0718 / Dr. Monica Vilela Heimer (81) 9 9969-1160 / Dr. Mabel Cristina Paiva M. Silva (81) 9 8779-5017. All of them have their professional address at: Av. Gov. Agamenon Magalhães - Santo Amaro, Recife - PE, 50100-010. If your questions are not resolved by the researchers or your rights are denied, please contact the Human Research Ethics Committee, CEP: Av. Agamenon Magalhães, S/N, Santo Amaro, Recife-PE, or by phone: (81) 3183-3657 or by email: Comitê.etica@upe.gov.br.

We ask for your understanding and cooperation by authorizing your participation in the examination and intervention in the box below.

I, _____, having received all clarifications and being aware of my rights, agree to participate in this research and authorize the disclosure and publication of all information transmitted, except personal data, in scientific publications and events. I therefore sign this agreement, together with the researcher, in two identical copies, with one copy remaining in my possession and the other in the possession of the researcher(s).

Location: _____ Date: ___/___/___

Participant's signature Principal investigator's signature

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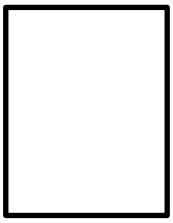


APPENDIX C - SURVEY FORM

SEARCH FORM

I – Identification

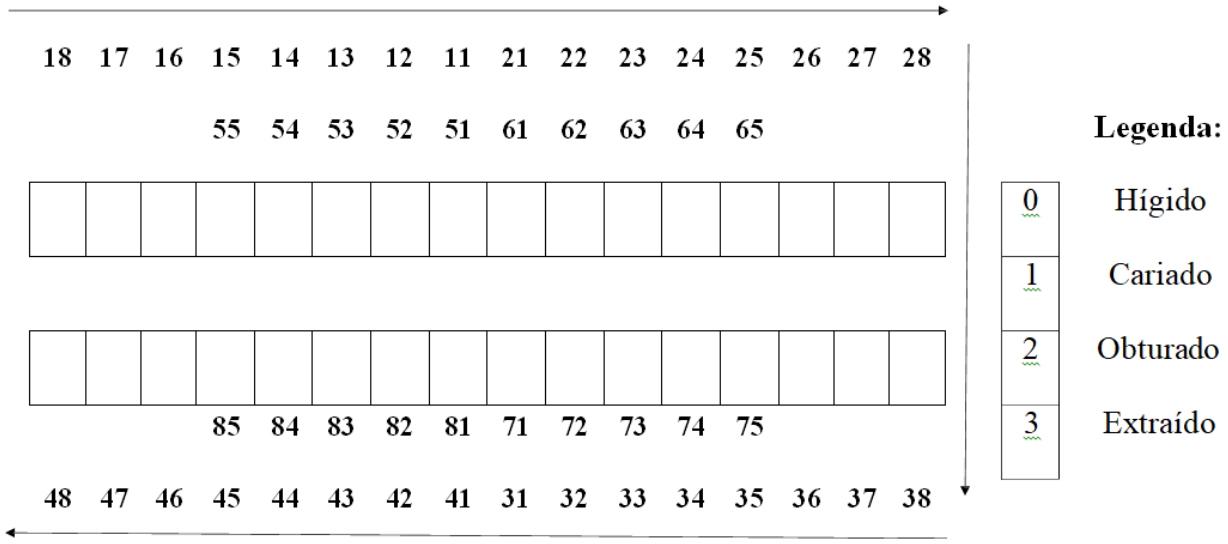
1) Child's Name: _____

2) Guardian: _____

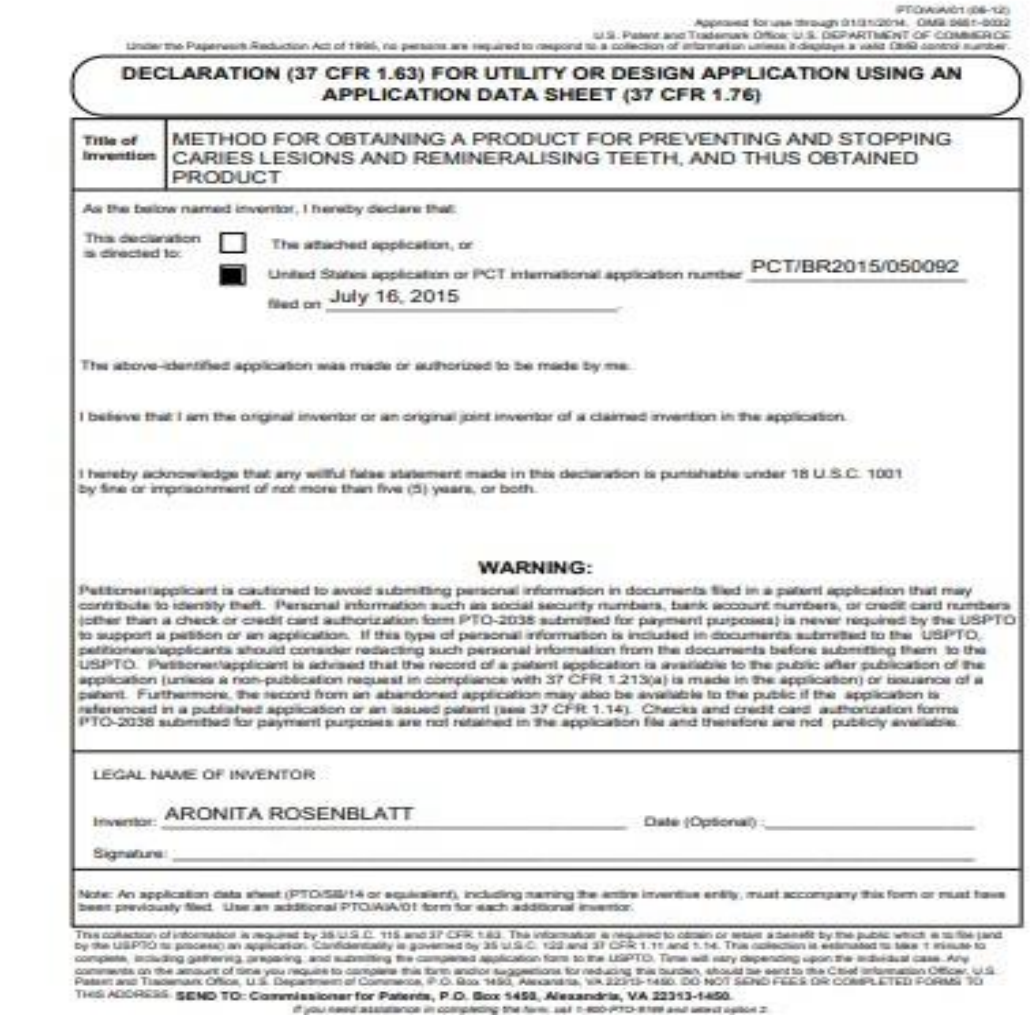
3) Telephone: _____

4) Age: _____

5) Sex: 1.( ) Male 2.( ) Female



ANNEX A – PRODUCT PATENT DECLARATION



PTO/AIA/01 (06-12)
Approved for use through 01/31/2014. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN APPLICATION DATA SHEET (37 CFR 1.76)

Title of Invention	METHOD FOR OBTAINING A PRODUCT FOR PREVENTING AND STOPPING CARIES LESIONS AND REMINERALISING TEETH, AND THUS OBTAINED PRODUCT

As the below named inventor, I hereby declare that:

This declaration is directed to: ☐ The attached application, or

☒ United States application or PCT international application number PCT/BR2015/050092

filed on July 16, 2015

The above-identified application was made or authorized to be made by me.

I believe that I am the original inventor or an original joint inventor of a claimed invention in the application.

I hereby acknowledge that any willful false statement made in this declaration is punishable under 18 U.S.C. 1001 by fine or imprisonment of not more than five (5) years, or both.

WARNING:

Petitioner/applicant is cautioned to avoid submitting personal information in documents filed in a patent application that may contribute to identity theft. Personal information such as social security numbers, bank account numbers, or credit card numbers (other than a check or credit card authorization form PTO-2038 submitted for payment purposes) is never required by the USPTO to support a petition or an application. If this type of personal information is included in documents submitted to the USPTO, petitioners/applicants should consider redacting such personal information from the documents before submitting them to the USPTO. Petitioner/applicant is advised that the record of a patent application is available to the public after publication of the application (unless a non-publication request in compliance with 37 CFR 1.213(a) is made in the application) or issuance of a patent. Furthermore, the record from an abandoned application may also be available to the public if the application is referenced in a published application or an issued patent (see 37 CFR 1.14). Checks and credit card authorization forms PTO-2038 submitted for payment purposes are not retained in the application file and therefore are not publicly available.

LEGAL NAME OF INVENTOR

Inventor: ARONITA ROSENBLATT Date (Optional): _____

Signature: _____

Note: An application data sheet (PTO/SB/14 or equivalent), including naming the entire inventive entity, must accompany this form or must have been previously filed. Use an additional PTO/AIA/01 form for each additional inventor.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ANNEX B – CONSOLIDATED OPINION OF THE CEP

HEMOPE

FUNDAÇÃO DE HEMATOLOGIA E HEMOTERAPIA DO ESTADO

Plataforma Brasil

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Titulo da Pesquisa: Técnica inovadora de aplicação de um produto sustentável para paralisar cárie em crianças no novo normal

Pesquisador: Aronita Rosenblatt

Área Temática:

Versão: 3

CAAE: 54240521.7.0000.5195

Instituição Proponente: FUNDACAO UNIVERSIDADE DE PERNAMBUCO

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 6.047.001

Apresentação do Projeto:

: Este estudo tem como objetivo comparar, através de um ensaio clínico randomizado, a eficácia na paralisação de cárie dentária da solução líquida para bochechos de Nano Fluoreto de Prata (NFP) 600 ppm, e um grupo controle exposto apenas ao dentifrício fluoretado de 1.500 ppm, transformando a tecnologia tradicional de uso binomial paciente/ profissional em tecnologia de uso individual. Metodologia: O estudo avaliará 360
crianças de 6 e 7 anos de idade, adstritas nas Unidades de Saúde da Família no município de Recife – PE. Será aplicado nas crianças um programa
de bochechos a cada 12 meses, sendo avaliadas para o progresso de cárie a cada seis 6 meses, durante 30 meses. O grupo controle, também será
avaliado no mesmo período. Para a análise estatística utilizaremos o índice ceo-d; os testes de Qui-quadrado de Pearson e Exato de Fisher e Testes de Kolmogorov-Smirnov e Mann-Whitney para comparar as variáveis quantitativas entre os dois grupos. Teste kappa será utilizado para determinar o grau de concordância intra e interexaminador

Objetivo da Pesquisa:

Objetivo Primário:

Comparar, através de um ensaio clínico randomizado, a eficácia na paralisação de cárie dentária da solução líquida para bochechos de NFP 600 ppm, e um grupo controle exposto apenas ao

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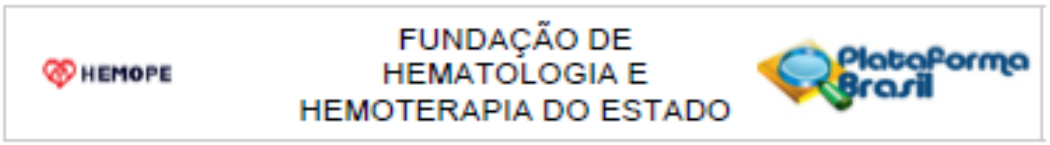
UF: PE **Município:** RECIFE
Telefone: (81)3182-4771 **E-mail:** cep@hemope.pe.gov.br



Continuação do Parecer: 6.047.001

dentifrício fluoretado de 1.500 ppm Objetivo Secundário:
• Transformar tecnologia tradicional de uso binomial paciente/ profissional em tecnologia de uso individual;• Avaliar o número de lesões de cáries paralisadas nos intervalos de 6 meses, 12 meses 18 meses, 24 meses e 30 meses em crianças participantes do programa de bochechos com
NFP com os não participantes, repetindo os bochechos a cada 12 meses;• Comparar os resultados obtidos no emprego da tecnologia de aplicação do produto com estudos anteriores, com a mesma concentração do NFP;• Avaliar o envolvimento da comunidade com iniciativa através do movimento de apoio de solicitação às autoridades sanitárias a não descontinuidade do programa.

Avaliação dos Riscos e Benefícios:

Riscos:
Com o risco da pesquisa, está o possível constrangimento da criança e dos pais em relação a possíveis perguntas, como a de escovação, bem como durante o exame clínico. Os participantes terão o direito de se recusar a responder a perguntas que causem constrangimentos de qualquer natureza. Além disso, pode ser que o paciente sinta algum incômodo durante o exame. Mas sem esse tipo de toque, não será possível perceber o
seu problema nem encaminhá-lo corretamente. Em relação aos bochechos, não há trabalhos na literatura, de riscos de envenenamento por deglutição do produto na concentração que será utilizada na pesquisa.
Benefícios:
Os benefícios esperados com o resultado desta pesquisa é gerar evidência científica sobre a eficácia da solução líquida para bochecho do NFP 600 ppm e assim transformar a tecnologia tradicional de uso binomial paciente/ profissional em tecnologia de uso individual, facilitando a manutenção da saúde bucal das crianças sem grande exposição à doenças virais. Além disso, caso alguma lesão de cárie não seja paralisada pelo produto
pesquisado, a criança será encaminhada para o seu tratamento.

Comentários e Considerações sobre a Pesquisa:

Metodologia Proposta:
Tipo de estudoTrata-se de um ensaio clínico "Real Life"52 de superioridade, seguindo as guidelines do CONSORT (Consolidated Standards of Reporting Trials).População e Amostra Crianças com 6 e 7 anos de idade, de ambos os sexos, adstritas em Unidades de Saúde da Família localizadas no Distrito Sanitário II do Município de Recife - PE, que apresentem ou não lesões de cárie. A escolha da faixa etária se justifica pela presença da dentição mista com os primeiros molares permanentes recém - erupcionados e pela

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UF: PE **Município:** RECIFE
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FUNDAÇÃO DE HEMATOLOGIA E HEMOTERAPIA DO ESTADO

Continuação do Parecer: 6.047.001

maturidade das crianças em não deglutir a solução em estudo. De acordo com o cálculo amostral, baseado na diferença de proporção relatadas em estudos anteriores53, com nível de significância de 5%, poder de teste de 95% e taxa de sucesso para o NFP 600 ppm foi de 67% será necessário avaliar 180 crianças em cada grupo, já incluindo

20% de prováveis perdas durante a pesquisa. Critérios de elegibilidade Critérios de Inclusão• Crianças com 6 e 7 anos de idade, livres ou não de cárie ativa em esmalte e dentina.Critérios de Exclusão • Crianças que apresentem algum tipo de síndrome que impeça a realização da pesquisa

Considerações sobre os Termos de apresentação obrigatória:

Termos obrigatórios apresentados ,tais como TCLE/TALE e Folha de rosto

Recomendações:

Não aplicável.

Conclusões ou Pendências e Lista de Inadequações:

Este parecer foi executado para retirar a pendencia da PB, porem o projeto ja foi finalizado.

Considerações Finais a critério do CEP:

Lembramos que o pesquisador (a) responsável assume o compromisso de encaminhar ao CEP da Fundação Hemope o Relatório Final baseado na conclusão do estudo e na incidência de publicações decorrentes deste, de acordo com o dispositivo nas normas vigentes, Resolução nº 510/16 e 466/12. O prazo de entrega do Relatório é de até 30 dias após o encerramento da pesquisa

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1866678.pdf	09/03/2022 15:58:58		Aceito
Folha de Rosto	folhaDeRosto.pdf	29/11/2021 14:08:54	Aronita Rosenblatt	Aceito
Projeto Detalhado / Brochura Investigador	PROJETONFP.pdf	26/11/2021 17:18:30	Aronita Rosenblatt	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLETALE.pdf	26/11/2021 17:18:16	Aronita Rosenblatt	Aceito

HEMOPE

FUNDAÇÃO DE HEMATOLOGIA E HEMOTERAPIA DO ESTADO

Plataforma Brasil

Continuação do Parecer: 6.047.001

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

RECIFE, 09 de Maio de 2023

Assinado por:
Maria Iraci Buarque Valença
(Coordenador(a))

Endereço: Rua Joaquim Nabuco, 171
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