Evaluation of the Antibacterial Effect of Nano Silver Fluoride versus Chlorhexidine on Occlusal Carious Molars Treated with Partial Caries Removal Technique: A Randomized Clinical Trial

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Thesis

Submitted to the Department of Conservative Dentistry

Faculty of Dentistry Cairo University

For Partial Fulfillment of the Requirements of Master Degree in

Conservative Dentistry

By:

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Faculty of Dentistry
Cairo University
(2019)

Introductory

I. Administrative information:

1. Trial registration:

Trial will be registered in www.clinicaltrials.gov

2. Protocol version:

Mar-2017.

3. Funding:

The trial will be self funded by the main researcher.

4. Roles and responsibilities

4.i. Ali Mostafa Shamaa

Role: Operator, data enterer and writing the research.

Affiliation: Master degree candidate in Conservative Dentistry Department, Faculty of Dentistry, Cairo University.

4.ii. Prof. Dr. Randa Hafez.

Role: Main supervisor, data monitoring, auditing

Affiliation: Professor, Conservative Dentistry Department, Faculty of Dentistry, Cairo University.

4.iii. Dr. Mai Mamdouh.

Role: Co-supervisor, data entry and auditing;

Affiliation: Lecturer, Conservative Dentistry Department, Faculty of Dentistry, Cairo University.

4.iv .Bacteriological assessment:

Department of Microbiology, Faculty of Medicine, Cairo University.

4.v. Mrs. Eman Desouky.

Role: Sample size calculation;

Affiliation: Statistician, Faculty of Dentistry, Cairo University, Egypt.

4.vi. Research Ethics Committee (REC)

Role: Protocol reviewer of the clinical trial in order to protect the right, safety, dignity and well-being of the participants;

Affiliation: Faculty of Dentistry, Cairo University.

Introduction

- **Scientific background:**

Dental caries is a disease that affects both children and adults. Though it has a known etiology which can be prevented and controlled, it remains a major health concern in industrialized and developing communities. It is dependent on dental plaque stagnation on the tooth surface. The bacterial constituents of the dental plaque are responsible for the metabolic activity needed for the development of carious lesion and demineralization of tooth structure. However, caries can be arrested if the biofilm is controlled but that mainly occurs at the tooth surface, as in the cavitated lesions there is a difficulty in hindering or disorganizing the bacterial biofilm.[1]

Therefore, restorative intervention is needed which implicates the removal of carious tissue followed by restoration of tooth to regain surface integrity that enabling efficient removal of dental plaque.[2]

Traditional restorative techniques involve complete removal of carious dentin this is based on assumption that complete elimination of bacteria by complete caries removal is a must for the success of restoration. Also it may lead to extensive tooth loss and pulp exposure especially in deep caries teeth.[3]

Another technique is step wise excavation in which partial removal of carious dentin is made and the cavity sealed in the first visit till formation of tertiary dentin then a second visit is mandatory to remove the remaining carious tissue which adds additional cost and effort in the procedure.[4]

Moreover, there is several evidence indicating that total removal of carious tissue is not required to reach an arrested lesion state.[2] Thereby partial caries removal

technique is approached which is less invasive and aims at leaving the deeper layer of carious dentin followed by permanent restorative material. The main target of this technique is that these deeper layer of carious dentin will be arrested and layoff of tertiary dentin is stimulated with subsequent dentinal sclerosis, thus either the possibility of pulp exposure or additional procedures during reentry of the cavity is eliminated.[3]

However, by leaving a layer of carious dentine which contain viable bacteria, there is a liability for caries to stay active and even progress further. In addition to the sealing achieved by the restorative material, an application of antibacterial agent that reduce bacterial load, slow or arrest the present lesion will ensure the success of the partial caries removal technique.[5]

- **Statement of the problem:**

The aim of partial caries removal technique is to eliminate the problems of complete caries removal and step-wise excavation by leaving the deeper layer of carious dentin. This will help in arresting the lesion with subsequent remineralization of the infected dentin. However; leaving bacterial infected dentine may lead to recolonization and subsequent recurrent caries.[4]

Therefore, the application of an antibacterial agent prior to restoration of deep carious molar that eradicates viable bacteria in the remaining carious layer and aids in arresting carious lesion will ensure the success of the partial caries removal technique.[5] Chlorhexidine is one of the most commonly used antibacterial agent. However, the use of chlorhexidine has some potential drawbacks like altered taste sensation, staining of teeth, and development of resistant bacteria that undermine its application.[6]

Several innovative approaches were made into developing antimicrobial agents that have bacteriostatic and bactericidal effects on the bacteria responsible for developing dental caries that may have a role in arresting carious lesions. A new agent which proven to be successful as antibacterial and in arresting existing caries is nano silver fluoride which is a new formulation that composed of silver nanoparticles, chitosan and fluoride that combines preventive and antimicrobial properties. This new formulation was proven to be safe and has shown good antimicrobial properties against cariogenic bacteria which helps in arresting carious lesion.[7]

- **Rationale:**

  The purpose of this study is to evaluate the antibacterial effect of nano silver fluoride solution on the carious dentin. This new formula is a promising anti-caries agent with low toxicity and ease of application in addition to its antimicrobial effect. This agent could help in caries arrest and decrease in the occurrence of secondary caries.

- **External validity:**

Benefits to patients/population:

1. Preserve pulp vitality.
2. Decrease the incidence of secondary caries.
3. Time and cost effective methods.

Benefits to practitioners/clinicians:

1. Noninvasive and conservative.
2. Avoid unnecessary removal of dentin tissues.
3. Time and money saving.

- **Objectives :**

The intention of this study is to evaluate the antibacterial action of nano silver fluoride solution application against oral streptococci mutans in comparison to chlorhexidine solution after partial caries removal in class I carious permanent molars.

- **Hypothesis:**

The null hypothesis tested in this study, that there is no difference between nano silver fluoride and chlorhexidine application on the bacterial count of oral streptococci mutans after partial caries removal in class I carious permanent molars.

- **Trial design:**

This investigation will be a randomized controlled clinical trial (RCT).

- **Trial type:**

Parallel study design.

- **Trial framework:**

Equivalence trial

- **Allocation ratio:**

1:1.

Review of literature

- **Search strategy**:
  - **Source**:

    The results have been searched in two data bases:

  - PubMed database and Scopus database.
  - **Date**: 16\03\2017

Index terms	**Mesh terms**
Deep carious lesion	Dentin caries Carious dentin
Nano silver fluoride	
Chlorhexidine	Chlorhexidine Chlorhexidine gluconate Chlorhexidine Hydrochloride Chlorhexidine Acetate Chlorhexidine thymol Chlorhexidine bigluconate Chlorhexidine digluconate
Bacterial count	Bacterial count Bacterial counts Bacterial load Microbiological analysis Microbial colony count Microbial colony counts Microbial colony forming units assays

	Microbial colony-forming units assays

- **Inclusion and exclusion criteria**

Inclusion Criteria	Exclusion criteria
• Articles based on clinical trials that report the antibacterial effect of nano silver particles. • Articles published in English • Articles published after 2006	• Articles based on any other assessment method. • Any other antibacterial agent used. • Articles published in any other language. • Articles published before 2006

	Search terms	Medline	Scopus
P	Dentin caries OR Deep cavities OR	52870	4409

	Deep caries lesion OR Carious dentin		
I	Nano silver fluoride OR NSF OR Nano silver OR Silver nanoparticles OR Silver nanoparticle OR Silver nano	19116	178478
C	Chlorhexidine OR CHX OR Chlorhexidine gluconate OR Chlorhexidine Hydrochloride OR Chlorhexidine Acetate OR Chlorhexidine thymol OR Chlorhexidine bigluconate OR Chlorhexidine digluconate	11640	3250
O	Bacterial count OR Bacterialcounts OR Bacterial load OR Microbiological analysis OR Microbial colony count OR Microbial colony counts OR Microbial colony forming units assays OR Microbial colony-forming units assays	553619	1770
P& I	(((((Dentin caries) OR Deep cavities) OR Deep caries lesion) OR Carious dentin)) AND ((((((NSF) OR Nano silver) OR Silver nanoparticles) OR Silver nanoparticle) OR Silver nano) OR Nano silver fluoride)	56	94

P & C	(((((Dentin caries) OR Deep cavities) OR Deep caries lesion) OR Carious dentin)) AND ((((((((Chlorhexidine thymol) OR Chlorhexidine digluconate) OR CHX) OR Chlorhexidine) OR chlorhexidine gluconate) OR Chlorhexidine Hydrochloride) OR Chlorhexidine Acetate) OR Chlorhexidine bigluconate)	785	0
P & I&O	((((((Dentin caries) OR Deep cavities) OR Deep caries lesion) OR Carious dentin)) AND ((((((NSF) OR Nano silver) OR Silver nanoparticles) OR Silver nanoparticle) OR Silver nano) OR Nano silver fluoride)) AND (((((((Microbial colony counts) OR Microbial colony-forming units assays) OR Microbial colony forming units assays) OR Bacterial count) OR Bacterial counts) OR Bacterial load) OR Microbiological analysis) OR Microbial colony count)	15	3
P&C&O	((((((Dentin caries) OR Deep cavities) OR Deep caries lesion) OR Carious dentin)) AND ((((((((Chlorhexidine	227	0

	thymol) OR Chlorhexidine digluconate) OR CHX) OR Chlorhexidine) OR chlorhexidine gluconate) OR Chlorhexidine Hydrochloride) OR Chlorhexidine Acetate) OR Chlorhexidine bigluconate)) AND (((((((Microbial colony counts) OR Microbial colony-forming units assays) OR Microbial colony forming units assays) OR Bacterial count) OR Bacterial counts) OR Bacterial load) OR Microbiological analysis) OR Microbial colony count)		
P& I& C& O	(((((((Dentin caries) OR Deep cavities) OR Deep caries lesion) OR Carious dentin)) AND ((((((NSF) OR Nano silver) OR Silver nanoparticles) OR Silver nanoparticle) OR Silver nano) OR Nano silver fluoride)) AND ((Chlorhexidine OR CHX OR Chlorhexidine gluconate OR Chlorhexidine Hydrochloride OR Chlorhexidine Acetate OR Chlorhexidine thymol OR Chlorhexidine bigluconate OR	0	0

	Chlorhexidine digluconate))) AND (((((((Microbial colony counts) OR Microbial colony-forming units assays) OR Microbial colony forming units assays) OR Bacterial count) OR Bacterial counts) OR Bacterial load) OR Microbiological analysis) OR Microbial colony count)		

- **Review of studies:**

dos Santos et al 2014[7]**,** conducted a randomized controlled clinical trial to evaluate the effectiveness of a Nano Silver Fluoride (NSF), applied once a year to arrest caries in children. One hundred thirty decayed primary teeth were randomly divided into two groups: NSF as the experimental agent and water as the control group. Teeth were clinically diagnosed and treated by one masked examiner and followed up at seven days and five and 12 months by another calibrated examiner who was blinded to the type of treatment. The criteria of the ICDAS II were followed to determine the activity of lesion and the diagnosis of caries. The Pearson's chi-square test was used to compare the groups during different follow-up exams. At seven days, 81% of teeth in the NSF group exhibited arrested caries, whereas in controls, no teeth had arrested decay ($p < 0.001$). After five months, the NSF group had 72.7% with arrested decay, and the control group had 27.4% ($p < 0.001$). At 12 months, 66.7% of the lesions treated with NSF were still arrested, while the control group had 34.7% remaining arrested ($p = 0.003$). The number need to treat at five months was two, and at 12 months, the number was three. It was stated that NSF formulation is effective to arrest active dentine caries and not stain teeth.

Fahadian et al 2016 [8], evaluated the effect of silver nanoparticles incorporated into acrylic baseplates of orthodontic retainers on Streptococcus mutans colony-forming units. The main outcome was to compare the number of S mutans colony-forming units between two groups of orthodontic patients at the debonding stage, in which one group wore orthodontic retainers which have silver nanoparticles incorporated into their acrylic baseplates while the other group received conventional orthodontic retainers. Swab samples were taken from the maxillary palatal side from the patient in the dental chair at retainer placement (T1, 1 week after debonding the fixed orthodontic appliance) and T2, 7 weeks later. Twenty-nine patients in the control group and 32 in the intervention group were analyzed. At T1, the intervention group had higher S mutans colony counts relative to the control group. Later, at T2 after 7 weeks there was a significant reduction of colonies in the intervention group. Finally it was concluded that adding silver nanoparticles to the acrylic plate of retainers had a strong antimicrobial effect against S mutans under clinical conditions.

Salas-López et al 2017[9], directed an experimental and clinical trial to evaluate the effects of pit and fissure sealant mixed with silver nanoparticles on dental caries, by means of monthly measurement of fluorescence with DIAGNOdent over six months. In the experimental phase, the adhesion and microleakage of the pit and fissure sealant experiment were evaluated. Two groups of 10 teeth, without serious carious lesions, were included. Group A received conventional Clinpro pit and fissure sealant (3M Espe, St. Paul, MN, USA), and group B received NNPs mixed with Clinpro pit and fissure sealant. For the clinical phase, a split-mouth study double blind clinical trial was performed on 40 children aged 6-10 years old with healthy, erupted permanent first molars. A conventional pit and fissure sealant or a

silver nanoparticle-mixed sealant was randomly placed. Repeated measures analysis was performed to detect presence of carious lesions was assessed using a pen-type laser fluorescence device, the DIAGNOdent pen (Kavo, Biberach, Germany). Conventional sealant presented an average microleakage of 30.6%, and the silver nanoparticle-mixed sealant showed 33.6% (P=NS). A three times greater reduction in fluorescence was found in the silver nanoparticles group compared to the conventional group ($P<0.05$). It was concluded by the author that silver nanoparticle-mixed sealant reduced tooth demineralization significantly and likely increased remineralization, compared to the conventional sealant.

Aim of the study:

The aim of this study is to evaluate the antibacterial action of Nano Silver Fluoride solution application in comparison to Chlorhexidine solution after partial caries removal in class I carious permanent molars.

PICOTS:

P= Deep class I carious molars.

I= Nano silver fluoride (Prepared in Nanotech Co., Egypt).

C= Chlorhexidine2 % solution (Cavity Cleanser, Bisco, USA).

O = Bacterial Count (Streptococcus Mutans) CFU/ml.

T = T_1 before application and T_2 after application in the same visit.

S= Randomized Controlled Trial, In-Vivo Comparative Study.

Outcome Name	Measuring Unit	Measuring Device
Bacterial count of (Strepto. Mutans)	**CFU/ml**	**Digital Colony Counter, Agar Diffusion test**

Research question:

Is the application of Nano Silver Fluoride solution after partial caries removal- compared to the Chlorhexidine- will minimize the bacterial count in dentin in permanent class I carious molars?

I. Materials:

1. Nano silver fluoride solution (Prepared in Nanotech Co., Egypt) based on silver nanoparticles, chitosan and fluoride. Each tooth will receive two drops of NSF with a micro brush, equivalent to a dose of 10 mg of the solution

2. Chlorhexidine digluconate 2 % solution (Cavity Cleanser, Bisco, USA). Moistens dentin surface after cavity preparation using a micro brush.

3. Rubber dam.

4. Hand spoon excavators.

5. High speed contra angle air-driven hand-piece.

6. Round and round end cylinder carbide and diamond burs.

7. Universal adhesive (Tetric® N-Bond Universal, Ivoclar Vivadent, Schaan, Liechtenstein). The adhesive wil be scrubbed into the tooth surface for at least 20 seconds. Followed by dispersing with oil- and moisture-free compressed air until a glossy, immobile film layer results. Light-cure for 10 seconds using a light intensity of ≥ 500 mW/cm^2.

8. Bulk-fill resin composite (Tetric® N-Ceram Bulk Fill, Ivoclar Vivadent, Schaan, Liechtenstein) placed in increments of up to 4 mm and cured in 10 seconds (≥ 1,000 mW/cm^2) or 20 seconds (≥500 mW/cm^2).

9. Medium, fine and extra fine finishing diamond stones and rubber polishing disks.

II. Methods:

II.1. Study setting

This clinical study will be held in the Clinic of Conservative Dentistry Department, Faculty of Dentistry, Cairo University, Egypt. The researcher will bear ultimate responsibility for all activities associated with the conduct of a research project including recruitment of patients, explaining and performing the procedures to them.

II.2. Eligibility criteria:

II.2.a. Eligibility Criteria of participants:

- **Inclusion Criteria of participants:**

1. 18 – 40 years.
2. Not received antibiotic therapy since 1 month before sampling.
3. Males or Females.
4. Good oral hygiene.
5. Co-operative patients approving the trial.

- **Exclusion criteria of participants:**

1. Pregnancy.
2. Systemic disease or severe medical complications.
3. Heavy smoking.
4. Xerostomia.
5. Lack of compliance.

II.2.b. Eligibility Criteria of teeth:

- **Inclusion Criteria of teeth:**

1. Class I deep caries lesions in permanent molar (reaching ≥ 1/2 of the dentin on radiographic examination).
2. Absence of spontaneous pain; negative sensitivity to percussion; and absence of periapical lesions (radiographic examination).

- **Exclusion criteria of teeth:**

1. Class II caries lesion.
2. Shallow or enamel caries.
3. Cuspal loss or caries beneath the gingival margin.

II.3. Variables of the study:

Table (1) Variables of study

Variable	Symbol	Refers to
Intervention	I	Nano silver fluoride solution
	C	Chlorhexidine 2 %
Time of dentin sample collection	T_1	Before the application
	T_2	After the application

II.4. Trial Description:

II.4.a Excavation protocol:

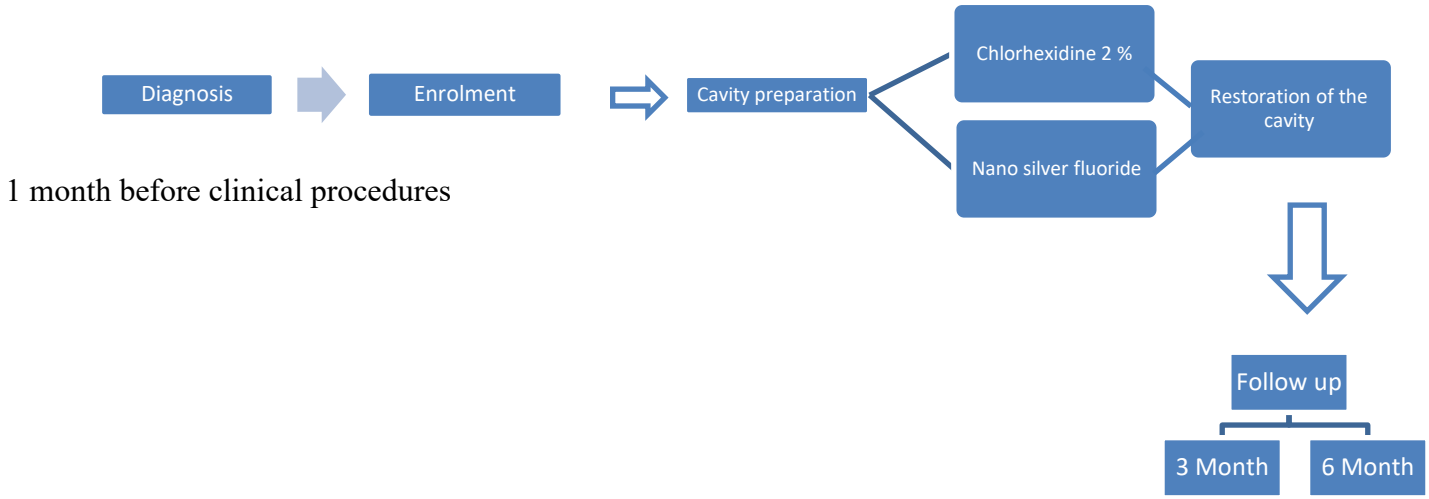
The teeth of the patients that meet inclusion criteria will be anesthetized, isolated with a rubber dam. Cavity opened using conventional high-speed rotary instruments. The central cariogenic biomass and the superficial parts of the necrotic dentine will be removed with round burs. Caries lesion will be completely removed in the enamel/dentin junction. The excavation procedure will be terminated as soon as the soft and wet dentine was removed and the remaining tissue was leathery but not hard on exploring. A dentinal sample will then be collected from the base of the cavity using sterile spoon excavator as a baseline for bacteriological assessment. Then, application of either intervention or control agent, another dentinal sample will be collected using a sterile excavator and transferred into sterile tubes and transferred to the laboratory for microbiological analysis.

II.4.b Assessment of Outcome:

Samples of carious dentine will be collected with sterile excavator before and after application of intervention/control agent. The dentine samples will be transferred to sterile container containing a 1mL thioglycollate medium used as a carrier, then this sterile container will be kept in an ice box and taken to the microbiology laboratory for processing, within an hour, by another examiner who is blinded to the type of agent applied after partial caries removal. Samples will be vortexed for two minutes, decimally diluted and 0.1 ml will be plated on Mitis Salivarius Bacitracin agar plates, these plates will be incubated anaerobically for 48 hour at 37ºC then aerobically for 24 hour at room temperature. The number of colonies will be expressed as colony–forming units (CFU/ml) compared before and after application of the antibacterial agent.

II.5. Participant timeline:

All clinical procedures will be carried out at the same visit.



1 month before clinical procedures

II.6. Sample size calculation:

The aim of this study is to evaluate the antibacterial action Nano Silver Fluoride solution application in comparison to Chlorhexidine solution after partial caries removal in class I carious permanent molar. Based on a previous study by ***Mohan et al. 2016***[5]**,** the expected difference between two interventions is expected to be 2.1±2.2CFU/mL × 10^3. Using power 80% and 5% significance level we will need to study 18 in each group to be able to reject the null hypothesis that the population means of the experimental and control groups are equal. This number is to be increased to 22 patients in each group to compensate for possible losses during follow up. The sample size was calculated by PS program.

II.7. Recruitment:

Patients will be recruited from outpatient clinic of Conservative Dentistry Department in Faculty of Dentistry, Cairo University; after explaining the benefits/risks from the application of the interventions, then eligible patients will be recruited to fulfil the eligibility criteria according to participant timeline.

II.8.a. Recruitment Strategy:

The patients will be subjected to full examination and diagnosis using dental charts. Once the patients that are potentially eligible for this study are identified, they will be contacted by the researcher who will explain the study and ascertains the patient's interest. If interested, more detailed evaluations and preparations are made.

II.9. Randomization and assignment of interventions:

II.9.a. Allocation sequence generation*:*

The allocation sequence will be generated using ***(www.randomization.com).***

II.9.b. Allocation concealment mechanism:

The randomization unit was the tooth, and the randomization procedure will be performed as follows. A number corresponding to each treatment group will be printed on pieces of paper and kept in dark containers. A paper will be selected from the container by a person other than the operator, and the treatment indicated will be performed (intervention/control). Blinding of the operator is not possible, because the color of intervention and control solution is different. The operator is blinded until randomization into groups, to avoid biases with regard to the application of antibacterial agent. Also, the examiner who will carry the microbiological analysis of dentin samples will be blinded to the type of agent

applied during treatment. Finally, the treatment results will be assessed blindly by a statistician.

II.9.c. Implementation:

Dr. Mai Mamdouh (co-supervisor) will perform the allocation sequence and assign the participants to the intervention/Control treatment group.

II.9.d. Blinding:

The side to which interventions or control is assigned to will be recorded and all records of all patients will be kept with the main supervisor. Blinding of the operator is not possible, because the color of intervention and control solution is different. The operator is blinded until randomization into groups, to avoid biases with regard to the application of antibacterial agent. Also, the examiner who will carry the microbiological analysis of dentin samples will be blinded to the type of agent applied during treatment. Finally, the treatment results will be assessed blindly by a statistician.

II.10. Data collection methods:

*Baseline data collection:

For every patient medical history, dental history and examination charts will be filled by the operator. The report will be anonymous where patients identified by their serial numbers (the first letter of the first and last name and date of birth) only will be registered. Full detailed personal data of the patient will be written in separate sheet having the patient's serial number for further contact with patient.

*Outcome data collection:

The results will be converted into a table to facilitate the description of the results. The microbiological analysis will be performed blindly in relation to the type of solution applied after partial caries removal.

II.11.Data management:

The data will be entered and stored on a personal computer. Double data entry will be saved on an external hard disc to prevent loss of data.

II.12. Statistical methods:

Data will be analyzed using IBM SPSS advanced statistics (Statistical Package for Social Sciences), version 21 (SPSS Inc., Chicago, IL). Numerical data will be described as mean and standard deviation or median and range. Categorical data will be explored for normality using Kolmogrov-Smirnov test and Shapiro-Wilk test. Comparisons between two groups for normally distributed numeric variables will be done using the Student's t-test while for non normally distributed numeric variables will be done by Mann-Whitney test. Comparisons between categorical variables will be performed using the chi square test. A p-value less than or equal to 0.05 will be considered statistically significant. All tests will be two tailed.

II.13. Monitoring:

II.13.a. Data monitoring:

The main supervisor will monitor this study. His role is to monitor any risk of bias could be done from participants, operator or assessors. Also to monitor blinding of the assessors and patient safety, outstanding benefits or harms.

II.13.b. Harms:

The main supervisor should inform participants about the possible harms, if present. Participants are allowed to contact the operator at moment through telephone. In case of accidental pulp exposure during excavation , emergency access cavity and pulp extirpation will be done by the operator and then the patient will be referred to Endodontic Department clinic to complete the rool canal treatment.

II.13.c. Auditing:

In the present trial, auditing will be done by the main and co-supervisors to assure quality of the research frequency procedures.

II.14. Ethics and dissemination

II.14.a. Research ethics approval:

Application forms for carrying out the clinical trial, checklist and informed consent of Research Ethics Committee (REC) Faculty of Dentistry, Cairo University will be retrieved and filled, then will be delivered for (REC) committee for approval. This is done to prevent any ethical problems during the study or any harm for any of the participants.

II.14.b. Protocol amendments:

If a new protocol will be used a protocol amendment will be submitted; containing a new copy of the new protocol and brief explanation about the differences between it and the previous protocols. If there is a change in the existing protocol that affects safety of subjects, investigation scope or scientific quality of the trial,

an amendment containing a brief explanation about the change will be submitted. If a new author will be added to accomplish the study, an amendment including the investigator's data and qualifications to conduct the investigation will be submitted to prevent ghost authorship.

II.14.c. Consent:

The operator (Ali Mostafa Shamaa) is responsible for admitting and signing the written consents during the enrolment day.

II.15. Confidentiality:

Name, personal data and pictures of the participants will not appear on the protocol form and will be maintained secured for 10 years after the trial. This is done for protection of participants' privacy and civil rights.

II.16. Declaration of interests:

There is no conflict of interest, no funding or material supplying from any parties.

II.17. Access to data:

Access to final data will be allowed to the operator ,the main and co-supervisors of the study who are not involved in assessment of the outcome.

II.18. Ancillary and post-trial care:

Patients will be followed up after the application after 3, 6 months.

II.19. Dissemination policy:

Full protocol will be published online in **www.clinicaltrials.gov** to avoid repetition and to keep the integrity of the research work. Thesis will be discussed in front of judgment committee. The study will be published to report the results of this clinical trial.

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Consent

الموافقه المستنيره للمتطوعين

عنوان البحث باللغة العربية: تقييم تأثير مضادات الباكتيري في مادة نانو الفضة الفلوريد مقابل الكلورهيكسيدين على الأضراس المتسوسة التي سبق معالجتها بتقنية إزالة جزئية للتسوس: دراسة أكلينيكيه عشوائيه.

الهدف من إجراء البحث:كبح البكتريا المسببة للتسوس قبل حشو الاسنان.

مقدمة عن وما سيتم اجراؤه على المريض بالتفصيل (خطة العمل)

الخطوات قبل الجراحة : سيتم ملء الرسم البياني التشخيص بما في ذلك جميع البيانات عن تاريخ المريض الطبي، والتاريخ المرضي للأسنان، والصور الرقمية.

الخطوات التطبيقيه:

١- يتم ازالة التسوس بالطرق السليمة الجاري استخدامها و المتعارف عليها في ضرس مصاب بالتسوس.

٢- بعد الانتهاء من اتباع تقنية ازالة جزئية التسوس يتم استعمال مادة مضادة للباكتريا سواءا نانو الفضة الفلوريد أو الكلورهيكسيدين.

٣- يتم أخذ عينات من العاج قبل استعمال المادة بعدها ثم ارسالها الي المختبر من أجل التقييم الميكروبيولوجي .

٤- يتم حشو الضرس بالطرق المعروفة و يتم أختيار الحشو وفقا لكل حالة.

عدد الزيارات :زيارة واحدة

الفائدة المباشرة للشخص المتطوع:

التأكد من أزالة التسوس بتقنية تحافظ علي حيوية الضرس بجانب وضع الحشو فى نفس الزيارة.

الفائده العلميه والفائدة العامة المرجوة من البحث:

الوصول الي مضاد باكتيري فعال ضد الباكتيريا المسببة للتسوس.

الأعراض الجانبية و درجة المخاطر المتوقع حدوثها وكيفية التعامل معه:

الاعراض الجانبية المصاحبة لأي حالة حشو و ليس لطرق الدراسة اي أعراض جانبية او ضرر على المريض وفي حالة حدوث أي اعراض جانبية بسبب الحشو يتم الرجوع إلى الطبيب المعالج.

المعرفه الكامله للمريض بخطوات البحث: **قراءة [ ] شرح شفهي [ ] أخرى [ ]**

اسم الباحث:علي مصطفى شمعة

اسم المتطوع

١- لقد اطلعت بعناية وفهمت الغرض من إجراء البحث وطبيعة هذه الدراسة ، وأنا أفهم ما هو ضروري لإنجاز هذه الإجراءات.
٢- قد أعلمنى الطبيب الباحث بالبدائل العلاجية الممكنة لهذا البحث
٣- لقد أبلغنى الطبيب الباحث بجميع المخاطر المحتملة لهذا البحث و كيفية التعامل معها.
٤- أوافق على التصوير والتسجيل ، وجميع أنواع الأشعة والتي يتعين القيام بها فى هذا الدراسة ، بشرط عدم الكشف عن هويتي.
٥- لقد قدمت تقريرا دقيقا عن تاريخ حالتى الصحيه. وأبلغت الطبيب بجميع أنواع ردود الأفعال الصحية أو الحساسية غير العادية من الأدوية أوالأغذية أولدغ الحشرات أومواد التخدير أوالغبار أو أى ردود أفعال حدثت لى من أى مواد أخرى ، أونزيف غير طبيعي أو أي ظروف أخرى ذات صلة على صحتي
٦ - أقر بأننى غير مشترك فى أى بحث أخر منذ بداية هذا البحث و حتى إنتهائه و أننى سأعلم الطبيب الباحث لو دخلت أى بحث أخر طوال فترة هذا البحث.
٧- أتعهد باعادة الأجهزة (الأدوات) الطبية المستخدمه في البحث في حالة التوقف أو عند انتهاء البحث.
بعد معرفة المعلومات المتاحة الخاصة بالبحث يتفضل الشخص المتطوع أو المسئول عنه بالاختيار بحرية ما بين الاشتراك من عدمه. في حال الموافقة يتفضل بملء البيانات الموضحة . من حق المتطوع الإنسحاب من البحث بدون إبداء الأسباب مع مراعاة حق إسترجاع الباحث لأى أجهزة أو أدوات طبية مستعملة بغرض البحث بحوزة المتطوع (تسمى من قبل الباحث)

<u>تعهد الطبيب المسئول عن البحث بالحفاظ على سرية المعلومات الخاصة بالشخص المتطوع بالمشاركة في البحث مع ذكر الطرق المستخدمه لذلك مثل استبدال الاسماء بارقام كوديه أو اخفاء معالم الوجه عند التصوير الفوتوغرافي ان امكن (الخ..)</u>

<u>من حق المتطوع الاحتفاظ بنسخه مصورة من الموافقه المستنيرة للبحث الذي تطوع فيه</u>

اسم المتطوع: تاريخ الميلاد:
الرقم القومي (ان وجد)
اسم ولي الأمر أو المرافق(عند اللزوم): الرقم القومي:
العنوان: الهاتف:
التاريخ:

توقيع الباحث: **التاريخ:**

توقيع المشرف على البحث (في حالة الرسائل): **التاريخ:**

بيانات تملأ بمعرفة اللجنة

هذا البحث تمت موافقة اللجنه عليه برقم

اسم الباحث:علي مصطفى شمعة اسم المتطوع