Cairo University
Faculty of Dentistry
Research Ethics Committee

جامعه القاهرة
كلية طب الأسنان
لجنه أخلاقيات البحث العلمي

CLINICAL EVALUATION OF THREE DIFFERENT BIOACTIVE RESTORATIVE MATERIALS IN CERVICAL CARIOUS LESIONS IN HIGH CARIES RISK PATIENTS:
A Randomized Controlled Clinical Trial

Protocol submitted to

Faculty of Dentistry, Cairo University
for partial fulfillment of the requirements **for the PhD Degree** in Restorative and Esthetic Dentistry.

By

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Theme .Objective code: CONS 3.7.5
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Human Subjects Application Form

Kindly fulfill the following:

Research title: CLINICAL EVALUATION OF THREE DIFFERENT BIOACTIVE RESTORATIVE MATERIALS IN CERVICAL CARIOUS LESIONS IN HIGH CARIES RISK PATIENTS.

Full name of the researcher(s): Ahmed Abdul Monsif Abdul Mohsen Abdul Aziz

Affiliation of the researcher(s): Main Supervisor: **Dr. Ashraf Nasr**
Co Supervisor: **Dr. Yehia Hafez**

Category of study: ***Master*** [ ] ***PHD/D*** [✓] ***Others*** [ ]

Type of study design: A Randomized Controlled Clinical Trial

Objective of the research : clinically evaluate three different bioactive restorative material in cervical carious lesion in high caries risk patients. Reducing the incidence of recurrent caries is the primary outcome.

Steps of the research in short including the following:

- ***The inclusion and exclusion criteria for patient selection:***

Inclusion Criteria:

- Patient age range from 25-45 year.
- High risk caries.
- Patients required at least a couple of Class V restorations.
- The depth of lesion should be (1.5- 2 mm).
- The patient should have good general health

Exclusion Criteria:

- Poor oral hygiene.
- Sever or chronic periodontal disease or Bruxism.
- Severe tooth sensitivity.
- Non-vital or fracture or cracked teeth.
- Defective restorations, orthodontic treatment or bleaching procedures during the last 6 months.

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- pregnancy, and/or lactation, and allergy to the main components of the products to be used in the study

- ***source of the patients enrolled in the research:***
  Patients that come to the Conservative Dentistry Department seeking dental care will continue until the target population is achieved. The patients will be subjected to examination and diagnosis.

- ***The place where the research will be conducted:***
  Conservative dentistry department clinic at Cairo University.

- ***Description of the methodology.***
  Local anesthesia will be applied when necessary. The operating field will be isolated using rubber dam, all caries will be removed, and box-shaped cavities will be prepared using high speed contra-angled hand piece with water cooling. All restorative materials will be applied according to the respective manufacturer's instructions.

- ***Sample size calculation.***
  The minimum sample size needed was 24 per group in order to detect a difference of 30%. Sample size was increased by 10% to compensate for possible dropouts to reach 27 teeth per group. Sample size was performed using G*Power version 3.1.9.2 for windows

- ***Randomization in case of RCT.***
  Each participant will choose a random number from an opaque sealed envelope. When the participant chooses an envelope, it will be signed and the supervisor and the number on the envelope will be recorded in the patient chart to ensure that the patient is assigned to the randomized group.
  Randomization will be done using simple randomization by computerized sequence generation using www.random.org by generating numbers from 1:30 into three columns.

- ***Number of visits & follow up period.***
  All restorations will be subjected to a clinical follow-up schedule representing four follow-up periods: (After 24 hours (baseline), 6 months, 12 months and 18 months).

Direct benefit of the research to the human volunteer: Reducing the incidence of recurrent caries.

The scientific interest and the desired public benefit of the research: will help in reduced risk of secondary caries or further decay on cervical lesions in high caries risk patients

Side effects and the degree of risk and expected to occur and how to deal with them: The procedures performed offer minimal risk to the oral health of patients, The adverse effects are represented by

the teeth with pain episodes, postoperative sensitivity, and tooth fracture during the restorative procedure, teeth requiring endodontic treatment.

Patient's full knowledge of the research steps: Reading [✓] Oral explanation [ ] Other [ ]

1. **I have carefully reviewed and understood the purpose of conducting the research and the nature of this study, and I understand what is necessary to accomplish these procedures.**
2. **The researcher has informed me of the possible therapeutic alternatives for this research.**
3. **The researcher has informed me of all the possible risks of this research and how to deal with it.**
4. **I agree to the imaging, recording, and all types of radiology to be performed in this study, on condition of anonymity.**
5. **I have made an accurate report on my health history and informed the doctor of all kinds of health reactions or unusual allergies to medicines, food, insect bites, anesthetics, dust or any reactions that have occurred to me from any other substances, abnormal bleeding or any other related conditions for my health.**
6. **I acknowledge that I am not involved in any other research from the beginning of this research until the end of this research and that I will inform the researcher if I enter any other research throughout the period of this research.**
7. **I undertake to return the medical devices (instruments) used in the research in case of discontinuation or when the research is completed.**

After knowing the available information related to the research, the volunteer or the person in charge will be able to choose freely whether or not to subscribe. In case of approval, kindly fill out the data shown. The volunteer has the right to withdraw from the research without giving reasons anytime.

The researcher in charge of the research undertakes to keep the information of the volunteer person confidential by participating in the research, stating the methods used, such as replacing names with code numbers or hiding facial features when photographing (etc.).

Signature:

Date:

هذا البحث تمت موافقة اللجنه عليه برقم
