



Human Subjects Application Form

Kindly fulfill the following:

Research title: CONCENTRATED GROWTH FACTOR VERSUS PLATELETS-RICH FIBRIN IN REVASCULARIZATION OF IMMATURE NECROTIC MANDIBULAR FIRST PERMANENT MOLAR.

Full name of the researcher(s): Bothaina Ahmed Ibrahim Ahmed

Affiliation of the researcher(s):

Main Supervisor: Assistant Prof. Ahmad Abdel Hamid Abdel Kader Elheeny

Co Supervisor: Dr. Kareem Mohamed Mahmud Eissawy

Category of study: Master [] PHD/D [☒] Others []

Type of study design: Parallel Randomized Controlled Trial

Objective of the research: compare and evaluate clinically and radiographically the effect of CGF and PRF with the application of biodentine on regeneration of necrotic immature lower first permanent molar.

Steps of the research in short including the following:

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

Inclusion Criteria:

- Children with immature necrotic lower first permanent molar.
- No history of repeated pathosis or cellulitis.
- Patients accept the treatment modality.
- Patient-free from systemic, allergic or genetic problems.

Exclusion Criteria:

- Tooth mobility.
- Teeth with non-restorable crowns.
- Children with facial cellulitis
- Children with draining fistula
- Children with a history of recurrent preapical pathosis.



- **source of the patients enrolled in the research:**

Patients that come to the the Pediatric and Community Dentistry Department, Minia University, The patients will be subjected to examination and diagnosis.

- **The place where the research will be conducted:**

Pediatric and Community Dentistry Department, Minia University.

- **Description of the methodology.**

Local anesthesia will be applied. The operating field will be isolated using rubber dam, all caries will be removed, cavities will be prepared using high speed contra-angled hand piece with water cooling. Access cavity preparation and remove the necrotic tissue in the pulp chamber. Disinfection of the root canal is accomplished by gently irrigating, The prepared CGF/PRF fractions will be inserted into the root canal space using a small hand plugger

- **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), 3 months, 6 months, 12 months and 18 months).

Direct benefit of the research to the human volunteer: Restore tooth vitality, complete root formation

The scientific interest and the desired public benefit of the research: assessment of the clinical success of PRF/CGF in pulp regeneration.

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 pain, 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 اللجنة عليه برقم : (1159) بتاريخ 2025/7/28

minia University

Faculty of Dentistry

Research Ethics Committee

جامعة المنيا

كلية طب الأسنان

لجنة أخلاقيات البحث العلمي



Faculty Dentistry

كلية معتمدة من الهيئة القومية لضمان جودة التعليم والاعتماد

بتاريخ 2024/9/25

جامعة المنيا
كلية طب الأسنان
لجنة أخلاقيات البحث العلمي

رؤية الكلية :
"تسعى الكلية إلى أن تحافظ على ريادتها في مجال طب الأسنان والبحث العلمي وخدمة المجتمع على المستوى القومي وتطلع إلى الريادة والارتقاء على المستوى الإقليمي والارتقاء إلى المستوى الدولي"

السيد الاستاذ الدكتور / وكيل الكلية لشئون الدراسات العليا والبحث العلمي

تحية طيبة وبعد،،،،

نحيط علم سيادتكم بقرار لجنة أخلاقيات البحث العلمي علي مشروع البحث المقدم من الطيبة/ بنية احمد إبراهيم احمد بقسم طب اسنان اطفال وصحة المجتمع للحصول علي درجة الدكتوراة بعنوان

Concentrated growth factor versus platelets- rich fibrin in revascularization of Parallel Randomized Controlled immature necrotic mandibular first permanent molar Trial

وذلك في الاجتماع رقم (١٢٠) للجنة أخلاقيات البحث العلمي بحث رقم (١١٥٩) لسنة ٢٠٢٥ والذي انعقد يوم الاثنين الموافق ٢٨ /٧/ ٢٠٢٥

القرار:- الموافقة مع اجراء التعديلات على نماذج اللجنة.

رئيس اللجنة

أ.د/ خالد بركات

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