Assessment of Clinical Success and Post-operative Pain of Mature Necrotic Teeth with Chronic Apical Periodontitis after Single Visit Regenerative Endodontics Using Different Irrigation Protocols: A Randomized Controlled Clinical Trial

A Thesis Protocol

Submitted for partial fulfillment of the requirements of the

Doctorate Degree in Dental Sciences in Endodontics

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Submitted By

Sarah Abdellatif Hamed Abdou

B.D.S., Faculty of Dentistry, Mansoura University (2013)
M.D.Sc. in Endodontics, Faculty of Dentistry, Suez Canal University (2023)
Assistant lecturer in Department of Endodontics, New Mansoura University.

Supervisors:

Title	Name	Job Title	University	Signature
Prof.	**Hayam Youssef Hassan**	Professor of Endodontics, Faculty of Dentistry	Suez Canal University	
Prof.	**Reham Mohamed Saeed Sayam**	Associate Professor of Endodontics, Faculty of Dentistry	Badr University in Egypt	

Faculty of Dentistry
Suez Canal University
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"Thesis Research Protocol"

Student Name:	Sarah Abdellatif Hamed	**Student ID:**	29107251200066
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Degree:	☐ **M.DSc** ☒ **D.DSc** ☐ **PhD**		
Department:	**Endodontic department**		
Thesis Title in English:	Assessment of Clinical Success and Post-operative Pain of Mature Necrotic Teeth with Chronic Apical Periodontitis after Single Visit Regenerative Endodontics Using Different Irrigation Protocols: A Randomized Controlled Clinical Trial		
Thesis Title in Arabic:			

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

1. Abstract

Introduction: Mature non-vital teeth have been treated with conventional root canal therapy, which leads to loss of protective mechanism and discoloration. Regenerative endodontic treatment (RET) has been successfully used in immature teeth; researchers have begun to apply it in mature teeth. Challenges facing (RET) in mature teeth include fewer stem cells and difficulty in disinfection. Sodium hypochlorite has been the most commonly used irrigant due to its antimicrobial and tissue-dissolving ability, but at a high concentration, it has a cytotoxic effect. Chitosan is a naturally present biocompatible polysaccharide with antimicrobial and chelating effects.

The use of the sensibility test, molecular markers, and radiographs provides a comprehensive view of the effect of different irrigation protocols on the success of mature teeth regeneration. Additionally, assessing postoperative pain using Numerical Rating Scale (NRS) offers a patient reported evaluation of treatment outcomes.

Aim: The study compares clinical outcome and postoperative pain levels using three different irrigation protocols in single visit regenerative endodontics.

Methodology: This randomized clinical trial involves 60 adult patients with necrotic mature anterior teeth divided into three groups based on the final irrigation protocol: 2.5% sodium hypochlorite and 17% EDTA, 1% chitosan nanoparticles and 1% chitosan nanoparticles and 17% EDTA. Postoperative pain is assessed using the Numerical Rating Scale at 6, 12, 24, 48 hours, and daily for 7 days. Clinical and radiographic follow up will be evaluated for all groups after 6 and 12 months. Statistical analysis comparing clinical outcome, pain levels, and their correlation across the groups will be done.

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

2. Introduction and Background

Conventional root canal treatment has been the first line of treatment of mature non-vital permanent teeth which includes preparation of the root canal chemo-mechanically and sealing with biocompatible materials **(Ng *et al.,* 2007)**. Loss of pulp tissue vitality and protective mechanism of proprioception, increase brittleness of teeth that had undergone root canal therapy, loss of translucency and discoloration are the drawbacks of conventional root canal treatment **(Gupta *et al.,* 2015)**.

Regenerative endodontic procedures (REP) have been used in the treatment of immature permanent teeth with necrotic pulp as a replacement for apexification **(Nosrat *et al.,* 2012)**. In regenerative endodontic procedure, the triad of tissue engineering is a combination of stem cells, scaffolds and growth factors which are utilized to aid regeneration **(Al-Haddad *et al.,* 2022)**.

In a disinfected root canal, intentional induction of bleeding from periapical tissue to form a blood clot creates a three-dimensional scaffold that entraps undifferentiated stem cells from the apical papilla, which utilize dentine growth factors to support the in-growth of new tissue **(Hargreaves *et al.,* 2008)**.

The main goal of conventional root canal treatment is elimination of clinical signs and symptoms with resolving periapical lesion which is the primary objective for RET as stated by American Association of Endodontics. The secondary and tertiary goals are increased thickness of the root wall and length, and regaining pulp vitality, respectively.

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

The tertiary goal could be considered as a desirable goal which is not essential for determining the success due to false positive and negative responses of the sensibility test **(Gopikrishna *et al.,* 2009).**

Thus, regenerative endodontics is a potential alternative to root canal therapy in mature necrotic teeth, utilizing primary and tertiary goals as a sign of success. Effective disinfection of the root canal is crucial for the success of RET **(Glynis *et al.,* 2021)**.

Single-visit RE procedures have been successfully reported in immature teeth where irrigation plays an important role in root canal disinfection, especially in the presence of apical periodontitis. In single-visit REP, success has been reported using high concentrations of sodium hypochlorite and Ethylene Diamine Tetra Acetic Acid (EDTA) with suitable activation techniques **(Abielhassan *et al.,* 2021)**.

Besides the clinical outcome and healing after using sodium hypochlorite and EDTA, chitosan nanoparticles and combination of chitosan nanoparticles and EDTA irrigants in single visit RE, pain following the treatment should be evaluated, which is influenced by irrigant type, concentration, and degree of extrusion using Numerical Rating Scale (NRS).

To our knowledge, no studies have compared clinical success and postoperative pain levels after using these different irrigation protocols in single-visit regenerative endodontics, contributing to create irrigation regimen. It also evaluates the regenerative potential of necrotic mature permanent teeth with chronic apical periodontitis after the one-step regenerative procedure.

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

3. Research Q (RQ)

What is the effectiveness of different irrigation protocols on clinical success and relieving postoperative pain after regenerative endodontic procedure in mature necrotic teeth with chronic apical periodontitis, as assessed by sensibility test, radiographs, molecular biomarkers and Numerical Rating Scale?

4. Research Hypothesis, Aim, Objectives & Expected Outcomes

a. Hypothesis

Null Hypothesis (H0): There is no significant difference between different irrigation protocols in terms of postoperative pain and clinical outcome.

Alternative Hypothesis (H1): There is a significant difference between different irrigation protocols in terms of postoperative pain and clinical outcome.

b. Aim

The study aims to evaluate and compare clinical outcomes and postoperative pain levels in necrotic mature teeth with chronic apical periodontitis after single visit regenerative endodontic procedure using different irrigation protocols.

c. Objectives

To compare and evaluate clinical success and postoperative pain levels in necrotic mature teeth with chronic apical periodontitis after single visit regenerative endodontic procedure using different irrigation

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

protocols through:

1. Clinical success via:
    a- Sensibility tests using cold test and electric pulp tester.
    b- Molecular markers (inflammatory mediators) from the gingival crevicular fluid (GCF) using ELISA.
    c- Radiographic analysis using Cone Beam Computed Tomography (CBCT).
2. Postoperative pain assessment using Numerical Rating Scale.

d. Expected Outcomes

Irrigation protocols in nano level are expected to demonstrate clinically successful outcomes, minimize postoperative pain, and flare-ups. The findings aim to highlight the regenerative potential of mature necrotic teeth with apical periodontitis using advanced irrigation protocols as an alternative treatment modality for conventional endodontic therapy.

5. Research Design and Methods

I. Materials:

Table (1): Materials, Description and Manufacturer

Type	Description	Manufacturer
Chlorhexidine di-gluconate	Disinfectant	DEXA company for chemicals
20% Benzocaine gel	Topical anesthesia	(Prime-Dent)
3% Mepivacaine	Plain anesthesia	Scandonest, Septodent, France
Rubber dam kit	clamp, sheet	(Coltene/Whaledent)
W&H RC-90 Key	High-speed handpiece	W&H (UK) Limited, Austria

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Endo-Z	Safe end carbide bur	MANI, Inc., Tochigi, Japan.
Br-31 Br-41	Round diamond bur	MANI, Inc., Tochigi, Japan.
#10 & #(15-40) K-file	Manual files	MANI, Inc., Tochigi, Japan.
E-PEX Pro	Apex locator	Eighteenth, Inc., Changzhou, China
Marathon e class	Endomotor	Saeyang, Korea
Sodium hypochlorite	Irrigant	Wilson, Sao Paulo, Brazil.
ProTaper Next	Rotary files	Dentsply Sirona, York, PA, Germany
Sterile disposable syringes	Irrigation equipment	AMECO company
Side-vented needles size #30 G	Irrigation equipment	Max-i- Probe, Dentsply Maillefer, Germany
Chitosan nanoparticles	Irrigant	Nanogate Company, Egypt
17% EDTA solution	Irrigant	META, BIOMED Co., LTD, Korea
Sterile paper points	Paper point ISO standard.	META, BIOMED Co., LTD, Korea
Collacote membrane	Absorbable collagen wound dressing	Zimmer Dental, USA
Well-Root PT	MTA bioceramic ready paste	Vericom, Korea
Light-cured resin-modified glass ionomer	Restorative material (base)	Riva, SD, Australia

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Etchant gel	37% phosphoric acid etch	META, BIOMED Co., LTD, Korea
Prime & Bond Universal	Universal adhesive bond	Dentsply Sirona, York, PA, Germany
Composite resin	Restorative material	Neo Spectra ST HV, Dentsply Sirona, Germany
Endo Ice	Cold vitality test	Maquira, Brazil
Electric pulp tester	Electric vitality test	Denjoy, China

II. Methods:

II. 1. Study Setting:

This study is an *in vivo*, prospective, double-blinded, randomized controlled clinical trial since it will be carried on 60 adult patients in the age range between 18 and 40 years having necrotic single-rooted anterior teeth with mature root and chronic apical periodontitis with evidence of apical radiolucency according to calculated sample size that will be mentioned later in (6. 1).

II. 2. Sample Selection:

The patients will be recruited from the outpatient clinic following CONSORT regulations, and treatment and follow-up will be done in the clinic of the Endodontic Department, Suez Canal University. Patients will be selected according to the following eligibility criteria:

Inclusion Criteria (El-Kateb *et al.,* 2020)

1. Adult patients in the age range 18–40 years with necrotic mature anterior teeth with chronic apical periodontitis as evidenced by apical radiolucency.

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2. Patients with good general health, without known systemic diseases or allergic reactions to any of the material used affecting healing outcome, with no sex predilection.

Exclusion Criteria (El-Kateb *et al.,* 2020)

1. Medically compromised patients, systemic conditions (e.g., uncontrolled diabetes), or those on immunosuppressive drugs.
2. Pregnant females.
3. Patients with generalized chronic periodontitis, mobility, and deep pockets.
4. Non-restorable teeth or teeth with open apices.
5. Teeth where a post is needed to be restored or with previous root canal therapy.
6. Teeth with developmental anomalies, external and internal resorption.

II. 3. Sample Grouping and Randomization:

60 adult patients will be randomly assigned into one of the three final irrigation groups as a final rinse using http://www.randomizer.org as follows:

Group 1: Irrigation with 2.5% Sodium hypochlorite + 17% EDTA (n=20).

Group 2: Irrigation with 1% Chitosan nanoparticles (n=20).

Group 3: Irrigation with 1% Chitosan nanoparticles + 17% EDTA (n=20).

Sonic activation of the irrigants will be done for all groups.

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II. 4. Study Procedures:

II. 4.1. Patient Preparation: (El-Kateb *et al.,* 2020)

Teeth will be cleaned and polished, and the patient will rinse with chlorhexidine di-gluconate.

Plain local anesthesia will be administered using 3% Mepivacaine without a vasoconstrictor.

Samples from the gingival crevicular fluid (GCF) will be taken to assess the level of the inflammatory mediators.

Rubber dam isolation will be performed, ensuring a clean field without leakage.

II. 4.2. Access Cavity Preparation:

Conventional access cavities will be prepared, allowing accessibility to the pulp chamber and root canals. Size #10 ISO K-files will be used to achieve canal patency. An electronic apex locator will be used for working length determination, which will be confirmed radiographically, 0.5-1 mm shorter than the radiographic apex.

II. 4.3. Root canal instrumentation:

The root canal systems will be prepared using ProTaper Next rotary files to the full working length till size X5.

The canals will be irrigated between every two successive files with 1.5% sodium hypochlorite (NaOCl) using a 30-gauge irrigation needle inserted 1 mm shorter than the working length.

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II. 4.4. Irrigation protocols:

Group1: Canals will be thoroughly irrigated by 2.5% NaOCl, followed by saline rinse then 17% EDTA.

Group 2: Canals will be thoroughly irrigated by 1% chitosan nanoparticles.

Group 3: Canals will be irrigated by 1% chitosan nanoparticles, followed by saline rinse then 17% EDTA.

All irrigation procedures will be done using a 30-gauge side vented needle placed 1 mm shorter than the working length.

II. 4.5. Regenerative procedures:

After canal dryness, an apical bleeding will be induced by intentional over instrumentation using precurved size #25 ISO K-file extended 2-3 mm beyond the apex **(El-Kateb *et al.,* 2020)**.

After blood clot formation, Collacote membrane will be placed over it, followed by Well Root MTA putty **(Ahmed *et al.,* 2023)**.

The tooth will be restored using glass ionomer and composite resin.

II. 5. Evaluation Methods:

1. **Clinical success (Nassar *et al.,* 2023)**:

a. Clinical sensibility tests using electric pulp tester and cold test at 6 and 12 months follow up periods.
b. Radiographic volumetric change at 6 and 12 months follow up periods.
c. Detection of the inflammatory mediators from the gingival crevicular fluid (GCF) at 6 months follow up period as a predictor of success or failure **(Garrido *et al.*, 2014)**.

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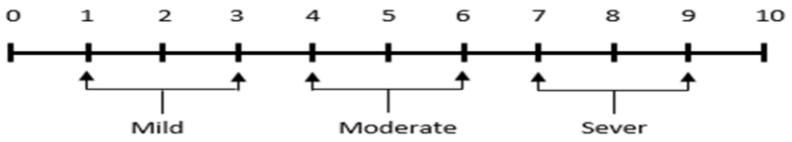
2. **Post-oprative pain assessment**: Using Numerical Rating Scale (NRS).

Patient will record their pain levels at 6, 12, 24 hours, then daily for 7 days postoperatively.

Pain data will be interpreted to give an idea about the relationship between the final irrigation protocol and the level of postoperative pain and flare ups.

The NRS includes scores from 0 to 10 on a 10 cm straight line ruler. Each centimeter represents the intensity of pain according to the following criteria **(Tawfik *et al.,* 2019؛ Abdelmougoud *et al.,* 2025)**

- (0): no pain.
- (1-3): mild pain.
- (4-6): moderate pain.
- (7-9): severe pain.
- (10): worst possible pain.



6. Statistical plan

6.1. Sample Size Calculation:

Current research was performed to compare three different treatment groups: 2.5% NaOCl+ 17% EDTA, 1% Chitosan nanoparticles and 1% Chitosan nanoparticles+ 17% EDTA at two different follow up periods

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(6-m, 12-m). The sample size was calculated using a computer software (G* Power) software version 3. 1. 5 **(Faul *et al.*, 2013)**. The sample size calculation yields a total of 60 samples using one way ANOVA test. According to sample size calculations, each treatment group would be represented by 20 samples as shown in table (2&3), based on the results of a previous study **(Akyüz *et al.*, 2025)**.

The following are details of the sample size calculation:

1. Effect size=0.42

2. Pooled SD=.381

3. Alpha (α)=.050

4. Power (β)=.80

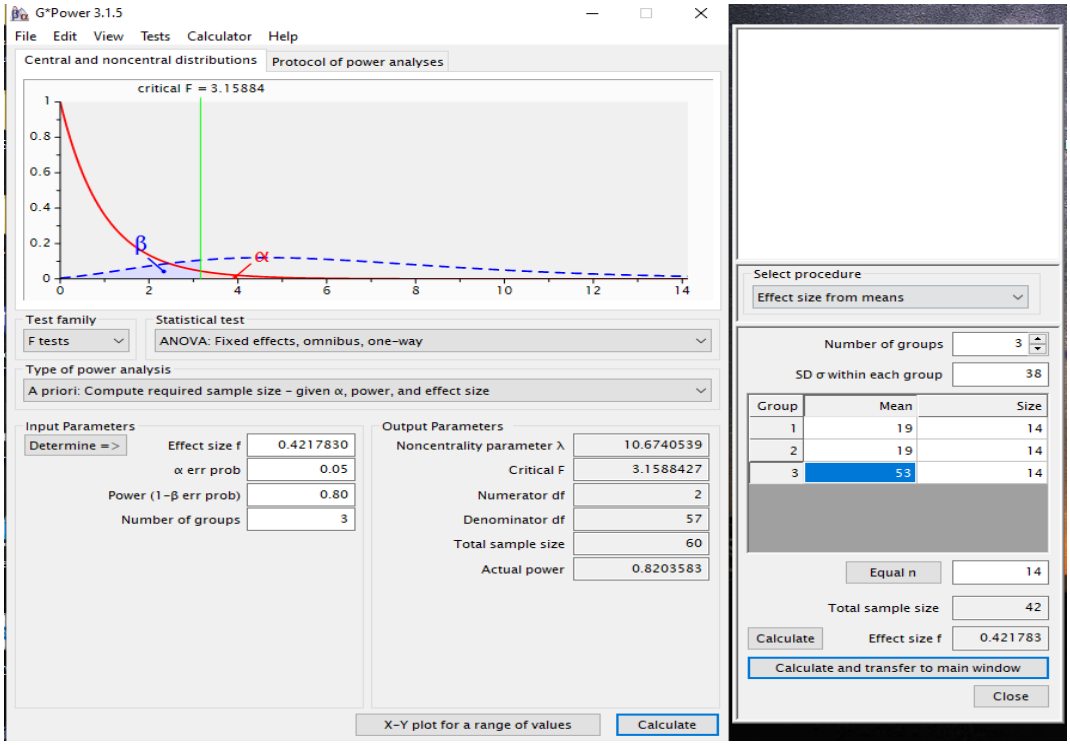

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Table (2): Variables of study

Variable	Symbol	Denote
Group (A)	A1	Group 1: Canals will be thoroughly irrigated by 2.5% NaOCl, followed by 17% EDTA.
	A2	Group 2: Canals will be thoroughly irrigated by 1% chitosan nanoparticles.
	A3	Group 3: Canals will be irrigated by 1% chitosan nanoparticles followed by 17% EDTA.
Follow up periods	6 m	6 months follow up period.
	12 m	12 months follow up period.

Table (3) interaction between study variables

Groups	Follow up periods		Total sample size
	6 m	12 m	
A1	A1 6m	A1 12m	20
A2	A2 6m	A2 12m	20
A3	A3 6m	A3 12m	20
Total	60	60	60

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6.2. Statistical Analysis:

The statistical analysis will be performed for comparison between three different treatment groups (A1, A2, A3): 2.5% NaOCl+ 17% EDTA, 1% Chitosan nanoparticles and 1% Chitosan nanoparticles+17% EDTA at two different follow-up periods (6m, 12m). The data will be collected, checked, revised and organized in tables and figures using Microsoft Excel 2019.

Data will undergo outliners' detections and normality statistical test to determine whether the data are parametric or non-parametric. Data will be subjected to descriptive statistical analysis both graphically and numerically.

Inferential statistics for assessing and comparing between three different groups (A1, A2, A3): 2.5% NaOCl+17% EDTA, 1% Chitosan nanoparticles and 1% chitosan nanoparticles+17% EDTA at two different follow-up periods (6m, 12m) will be performed by repeated measure analysis of variance (ANOVA) or corresponding non parametric analysis at significance level 5%. ANOVA will be followed by Bonferroni Post-hoc test to compare between treatment groups or corresponding test for non-parametric data.

Differences between the three treatment groups at each follow-up period will be performed by one way analysis of variance (ANOVA) or Kruskal-Wallis for non-parametric data at significance level 0.05. The difference between the two follow-up periods will be performed using paired samples t-test. Data analysis will be performed using computer software Statistical Package for Social Science SPSS (IBM-SPSS ver. 30.0 for Mac OS) (Knapp, 2017).

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

7. Ethics consideration

For Clinical Studies (*In-vivo* Studies)

The present research will be executed after the approval of the Research Ethics Committee (REC) of the Faculty of Dentistry, Suez Canal University. It will be conducted on 60 adult patients (18-40 years) having necrotic mature anterior teeth with chronic apical peridontitis. Ethical considerations regarding patient well-being and confidentiality will be undertaken by the researcher and an informed written consent will be signed by (parents in case of age < 21 years and patients in case of age > 21 years) before commencing the study explaining all clinical examinations, procedures and follow up (Attached appendix I).

8. Time Plan:

Include Gantt Chart as following example:

Starting: After faculty approval of the protocol.

Ending: Within 24 months

Activity/Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Patient selection	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Treatment procedure & follow up	☐	☐	☐	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☒	☐	☐	☐	☐	☐	☐	☐
Lab analysis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☐	☐	☐	☐	☐
Statistical analysis	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☐	☐	☐	☐
Thesis writing	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☒	☒	☒	☒

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

9. Research Estimated Budget in Egyptian Pound

Supplementary				Publications	**Total**
drugs/ Lab chemicals	Lab-investigations	Software	Material		
20000	50000	5000	60000	7000	142000

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Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

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Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

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Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com

11. Appendices

Suez Canal University
Faculty of Dentistry
Research Ethics Committee (REC)

Investigator Application Form

1-Name of researcher: Sarah Abdellatif Hamed Abdou.

2-Name of Department: Department of Endodontics, Faculty of Dentistry, Suez Canal University, Egypt.

3-Address of researcher: Endodontic Department, Faculty of Dentistry, Suez Canal University, Egypt.

Email: drsarahhamed25@gmail.com

a- Phone number: 01012604389
b- Fax number: ……...…...

4- Name (s) of Co-investigator (s)

Professor / Hayam Youssef Hassan

Professor of Endodontics, Faculty of Dentistry, Suez Canal University

Professor/ Reham Mohamed Saeed Sayam

Associate Professor of Endodontics, Faculty of Dentistry, Badr University

5- Grade of protocol:

*M.D.Sc. ( ) *Ph.D. ( ) *Doctorate degree (D. D.Sc.) (√) *Other ( )

*Domestic ( ) *Multi-Centre within Egypt ( ) *International ( )

6- Title of the research: Assessment of Clinical Success and Post-operative Pain of Mature Necrotic Teeth with Chronic Apical Periodontitis after Single Visit Regenerative Endodontics Using Different Irrigation Protocols: A Randomized Controlled Clinical Trial.

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7-Type of the research: An in-Vivo Study

*Drug trial (√) *Surgical technique ( ) *Investigative technique ( )

*Devise study ( ) *Survey study ( ) *Blood sampling ( ) *Review of old records ( )

8-Subjects of research:
*Children (< 18 years): ( ) *Adults (>18 years) (√)
* Vulnerable groups (yes) or (no)
9-Request is being made to ***waive*** (give up) informed consent: Yes: ( ) No: (√)

10- The research is for the good of society: Yes: (√) No: ( )
11-Study design:
a-Phase type I: (√) II: ( ) III: ( )
b-Randomization: Yes: (√) No: ( )
c-Placebo: Yes: ( ) No: (√)
d-Genetic sampling: Yes: ( ) No: (√)
e-Other: Yes: ( ) No: ( )
12-Facilities for the research are available: Yes: (√) No: ( )
13- List the risks of the study: pain, swelling and edema.
14- List the potential benefits, if any, to the subjects
Highlight the regenerative potential of mature necrotic teeth with apical periodontitis using advanced irrigation protocols as an alternative treatment modality for conventional endodontic therapy.
15-Are the risks reasonable to the potential benefits to the subjects, if any, or to the knowledge to be gained? Yes: (√) No: ( )

16-Privacy and confidentiality of subjects are assured. Yes: (√) No: ( )

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17-The subject of the research could quit at any time without penalty or loss of any benefit to which they would otherwise be entitled.

Yes: (√) No: ( )

Signature of the principal investigator:

Assistant lecturer:Sarah Abdellatif Hamed

Date: 31/3/2026

Tel: 01012604389 Fax: E-mail: drsarahhamed25@gmail.com