



SUEZ CANAL UNIVERSITY
FACULTY OF DENTISTRY
RESEARCH ETHICS COMMITTEE (REC)

STUDY PROTOCOL AND ETHICS
DOCUMENTATION

Official Study Title:	Metagenomic Analysis and Post-operative Pain Assessment of Infected Root Canals Using Different Irrigation Protocols: A Randomized Controlled Clinical Trial
NCT Number:	Not yet assigned (Initial Submission)
Document Date:	December 25, 2025
Ethical Approval No:	REC 928/2024
Principal Investigator:	Salma Mohamad Hassan Gohar



Research Title

Metagenomic Analysis and Post-operative Pain Assessment of Infected Root Canals Using Different Irrigation Protocols: A Randomized Controlled Clinical Trial

Introduction and Purpose

You are being invited to participate in a research study aimed at comparing four different methods (irrigation protocols) for cleaning infected root canals. The goal is to determine which method is most effective at reducing bacteria and minimizing pain after the procedure.

Study Procedures

If you agree to participate, the following will occur:

- Standard root canal treatment procedures will be performed under local anesthesia and aseptic isolation (rubber dam).
- You will be randomly assigned to one of four irrigation groups: Ultrasonic Activation, Laser Activation, Easy Clean device, or PulpSucker device.
- Small bacterial samples will be collected from your root canal before and after cleaning for laboratory analysis.
- You will be asked to record your pain levels using a simple 0-10 scale at 6 hours, 24 hours, 48 hours, and 7 days after the treatment.

Risks and Benefits

- Risks: There are no risks beyond those typically associated with standard root canal therapy. Any discomfort will be monitored.
- Benefits: You will receive advanced root canal irrigation techniques that aim to improve disinfection and treatment outcomes.

Confidentiality and ClinicalTrials.gov

Your identity and medical records will remain confidential. Data will only be used for research purposes. A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results.

6. Voluntary Participation

Participation is voluntary. You may withdraw from the study at any time without penalty or loss of benefits to which you are otherwise entitled.

Participant Signature

Date

Researcher Signature

Date



Investigator Application Form

1- Name of researcher: Salma Mohamad Hassan Gohar

2- Name of Department: Endodontic Department

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

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

5- Grade of protocol:

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

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

6- Title of the research:

Metagenomic Analysis and Post-operative Pain Assessment of Infected Root Canals Using Different Irrigation Protocols: A Randomized Clinical Trial

7- Type of the research:

An in-Vitro Study (Note: Clinical trial conducted in vivo)

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

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

8- Subjects of research:

*Children (< 18 years): () *Adults (>18 years) (yes)

*Vulnerable groups () yes or (X) no

9- Request is being made to waive (give-up) informed consent:

Yes: () No: (X)

10- The research is for the good of society:

Yes: (yes) No: ()

11- Study design:

a- Phase type I: (yes) II: () III: ()

b- Randomization: Yes: (yes) No: ()

c- Placebo: Yes: () No: (no)



d- Genetic sampling: Yes: (yes) No: ()

e- Other: Yes: () No: ()

12- Facilities for the research are available:

Yes: (yes) No: ()

13- List the risks of the study:

Nil

14- List the potential benefits, if any, to the subjects:

Limited research exists on the effectiveness of advanced irrigation protocols in reducing bacterial load and alleviating postoperative pain in infected root canals. Most studies focus on individual techniques, with insufficient evidence comparing ultrasonic activation, laser activation, negative pressure irrigation (PulpSucker), and mechanical activation (Easy Clean). This study aims to evaluate bacterial reduction and postoperative pain levels (VAS) and analyze changes in bacterial community composition using metagenomic analysis.

15- Are the risks reasonable to the potential benefits to the subjects, if any, or to the knowledge to be gained?

No risk. Yes: (X) No: ()

16- Privacy and confidentiality of subjects are assured:

Yes: (yes) No: ()

17- The subject of the research could quit at any time without penalty or loss of any benefits:

Yes: (yes) No: ()

Signature of the principal investigator : _____

Date: 25/12/2025