National and Kapodistrian University of Athens

School of Dentistry

TITLE OF PROPOSED PhD THESIS:

Clinical antibacterial efficacy and treatment outcome after implementing various root canal irrigating procedures

PhD STUDENT:

Papadopoulou Charalampia

DATE OF SUBMISSION:

Athens, 12/12/2022

INFORMED CONSENT FORM FOR PARTICIPATION IN RESEARCH OF THE SCHOOL OF HEALTH SCIENCES, DEPARTMENT OF DENTISTRY, OF THE NATIONAL AND KAPODISTRIAN UNIVERSITY OF ATHENS (EKPA)

Research Approval Number: _____

Program Title: Clinical antibacterial efficacy and treatment outcome after implementing various root canal irrigating procedures.
School/Department: Department of Dentistry, EKPA / Endodontics Laboratory
Principal Investigator (Name and Contact Number): Giorgos Tzanetakis - 6944326268
PhD Student: Charalampia Papadopoulou
Research Associates: Maria Georgopoulou, Anastasia Agrafioti

You are invited to participate in a research program supported by EKPA. The following information is provided to help you decide whether you wish to participate.

1. Purpose

The purpose of this research is to evaluate and compare the antibacterial efficacy of three different root canal final irrigation protocols (NaOCl 2.5% alone, NaOCl 2.5% + Passive Ultrasonic Irrigation (PUI), NaOCl 2.5% + XP-Endo Finisher) in reducing intracanal bacterial load, and to assess how these protocols influence the clinical healing outcome after one year.

2. Procedures

Your participation involves the following steps:

- You must have a single-rooted tooth diagnosed with pulp necrosis and radiographic evidence of apical periodontitis.
- After giving your consent, you will undergo standard clinical and radiographic examinations.
- Endodontic treatment will be performed across two main visits:
    - **First visit:** Clinical evaluation, X-rays, and explanation of study procedures (~30 minutes).
    - **Second visit:** Root canal treatment, during which microbiological samples will be collected at three different treatment stages (~1 hour 30 minutes).
    - **Follow-up visits:** At 6 and 12 months, clinical and radiographic reassessment will occur (~15 minutes each).
- Microbiological samples will be collected using sterile paper points inserted into the canal at three time points:
    - After initial saline irrigation,
    - After standard chemomechanical preparation,
    - After final irrigation (according to your group assignment).

All procedures follow standard endodontic protocols, with the addition of sample collection.

3. Exclusions

You cannot participate if:

- You have taken antibiotics within the last 3 months.
- You require antibiotic prophylaxis for dental treatments.
- You have previously root canal-treated teeth, cracked roots, or periodontal pockets deeper than 4 mm.

4. Risks and Discomforts

There are no expected risks associated with participation in this study.

If endodontic treatment fails (regardless of participation in the study), three treatment options are available:

1. Retreatment if improvement is possible.
2. Surgical intervention if retreatment is not viable.
3. Tooth extraction if neither option is acceptable to you.

Any of the above treatments will be decided in agreement with the treating dentist, and the cost will be covered by the regular fees at the Dental School.

5. Research Costs

There is no additional cost beyond the standard fees of the Department of Dentistry. Endodontic treatment expenses are included in these fees.

6. Benefits

- The necessary endodontic treatment will be performed.
- While there is no direct benefit to society, the study results may help improve antimicrobial treatment protocols, increasing the success rate of endodontic therapy.

7. Payment

No payment will be provided for participation in this study.

8. Alternative Treatments

The recommended treatment for your condition is endodontic therapy.

9. New Findings

If new information emerges during the study that may affect your decision to continue participation, you will be informed accordingly.

10. Confidentiality

All records will remain confidential. However, there is no guarantee that this information cannot be disclosed in a court or other legal proceedings. In such cases, your name will not appear in any reports or publications.

11. Limited Liability

All research involves risks, including potential physical harm. Despite precautions, complications may arise. If complications occur, the researchers will assist with medical or dental care, but the cost will be your responsibility or covered by your insurance. EKPA does not have a budget for compensation in case of injury or medical complications. Signing this form does not waive your legal rights.

12. Right to Withdraw

You can withdraw from the study at any time without affecting your right to receive treatment at the Department of Dentistry or any other privileges. Refusal to participate will not impact your access to care.

The principal investigator reserves the right to terminate your participation if unexpected reactions occur, instructions are not followed, or the study is discontinued.

13. Assurance of Answered Questions

If you have further questions about the study, you may contact the principal investigator, Giorgos Tzanetakis, on 6944326268.

This program has been reviewed and approved by the Research Ethics Committee of the Department of Dentistry at EKPA. For questions regarding the committee, you may contact the Department Chair via Ms. E. Koumoutsea at 210-746-1114.

I have read the above information and agree to participate in this research. I acknowledge that I will receive a copy of the signed consent form.

Participant or Legal Guardian Signature: _____
Date: _____

Researcher Receiving Consent Signature: _____
Date: _____
