

**RECEP TAYYIP ERDOĞAN UNIVERSITY FACULTY OF  
MEDICINE NON-INTERVENTIONAL CLINICAL RESEARCH  
ETHICS BOARD**



**Name of the Study: Effects of Different Irrigation Activation Techniques on the Healing of Large Periapical Lesions: A Randomized Controlled Study**

**Date: 01.06.2023**

**PLEASE READ CAREFULLY!**

You are invited to participate in our research. Before deciding to take part, you need to understand the purpose of the study and make a free and informed decision. Please read this information carefully and feel free to ask any questions you may have.

Participation in this study is entirely voluntary. You have the right to refuse participation or withdraw from the study at any time. Your participation will be interpreted as your consent to join the research. Do not feel any pressure while answering the questions on the forms. All information gathered will be used solely for research purposes.

**PURPOSE OF THE STUDY:** This study aims to compare the healing rates of single-rooted mandibular teeth with large periapical lesions of endodontic origin using different irrigation activation methods (sonic, ultrasonic, Er:YAG laser, manual dynamic activation), through fractal analysis of panoramic radiographs taken before treatment and one year after treatment.

**• WHAT ARE THE CONDITIONS OF PARTICIPATION?**

To be eligible for participation, the following criteria must be met:

Patients examined at Recep Tayyip Erdoğan University Faculty of Dentistry, Department of Endodontics

Patients aged 18 and over

Have accepted the Endodontic Consent Form and Study Participation Form

Diagnosed with apical periodontitis requiring primary endodontic treatment with a PAI (periapical index score) of 3 or higher in single-rooted mandibular teeth

Diagnosed with apical periodontitis requiring retreatment with a PAI score of 3 or higher in single-rooted mandibular teeth

Having good oral hygiene

Participants will be included based on the irrigation activation technique used during routine endodontic treatment.

**• WHAT KIND OF APPLICATION WILL BE DONE?**

Routine root canal or retreatment procedures will be applied. If necessary, irrigation activation techniques will be used.

**• WHAT ARE MY RESPONSIBILITIES?**

You must regularly attend treatment and follow-up appointments as part of the study.

**• WHAT IS THE NUMBER OF PARTICIPANTS?**

A total of 132 participants are planned to be included in the study.

**• HOW LONG WILL MY PARTICIPATION LAST?**

Endodontic treatment is expected to take approximately 1 hour. You will be asked to participate in a follow-up one year after treatment..

**• WHAT ARE THE POSSIBLE BENEFITS EXPECTED BY PARTICIPATION IN THE STUDY?**

Observing the effect of endodontic treatment and irrigation activation techniques on the healing of teeth with large lesions.

**• WHAT ARE THE POSSIBLE RISKS EXPECTED BY PARTICIPATION IN THE STUDY?**

No risks beyond routine root canal treatment complications are expected.

**• WHAT ARE THE DRUGS/NUTRIENTS KNOWN TO BE CONTROLLED TOGETHER DURING THE RESEARCH PROCESS?**

There are no known medications or foods that pose a risk.

• **UNDER WHAT CONDITIONS CAN I BE EXCLUDED FROM THE RESEARCH?**

You may be excluded if tooth extraction, apical surgery, or similar indications arise during treatment.

• **WHO IS LIABLE/RESPONSIBLE IN CASE OF ANY DAMAGE AND WHAT WILL BE DONE?**

The treating physician and their supervisor are responsible for any harm that may occur.

• **WHO SHOULD I CALL FOR PROBLEMS THAT MAY ARISE DURING THE RESEARCH PROCESS?**

If you have any questions or require additional information, please contact:

**Name:** Medine ÇİÇEK

**Position:** Research Assistant

**Phone:** +905442745525

• **WILL THE EXPENSES IN THE SCOPE OF THE STUDY BE COVERED?**

There is no cost to the patient for procedures covered in this study.

• **IS THERE AN INSTITUTION SUPPORTING THE STUDY?**

The study will be conducted within the Faculty of Dentistry at Recep Tayyip Erdoğan University.

• **WILL ANY PAYMENT BE MADE DUE TO MY PARTICIPATION IN THE STUDY?**

No payment will be provided.

• **WHAT SHOULD I DO IF I DO NOT AGREE TO PARTICIPATE IN THE STUDY OR LEAVE THE STUDY?**

Participation is entirely voluntary. Patients who do not agree to participate will not be included in follow-up measurements after routine treatment. You can withdraw at any time without having to state a reason, and without facing any negative consequences.

• **CAN CONFIDENTIALITY BE PROVIDED REGARDING INFORMATION REGARDING MY PARTICIPATION?**

Participant identity information will be kept confidential. Age, gender, and radiograph data will be used for statistical analysis.

**Consent to Participate in the Study:**

I have read the information provided above and understand the purpose and scope of the study, as well as my responsibilities as a volunteer. The researcher named below has explained the study to me both in writing and verbally, and I had the opportunity to ask questions and received satisfactory answers. I was also informed verbally of the possible risks and benefits. I understand that I may withdraw from the study at any time without having to give a reason and that doing so will not result in any negative consequences.

Under these conditions, I voluntarily agree to participate in this study without any pressure or coercion. I understand that refusing to sign this form will not affect any legal rights I may have. A signed and dated copy of this form has been provided to me.

VOLUNTEER		
NAME & SURNAME		SIGNATURE
ADDRESS		
PHONE & FAX		
DATE		

RESPONSIBLE RESEARCHER		
NAME & SURNAME	R.A. Medine Çiçek	SIGNATURE
ADDRESS	Recep Tayyip Erdoğan University Faculty of Dentistry, Department of Endodontics	
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DATE		