

## **INFORMED CONSENT FORM**

**Official Title:** Effect of Intracanal Cryotherapy and Metformin on Postoperative Pain in Teeth With Symptomatic Apical Periodontitis: A Randomized Clinical Trial

**Principal Investigator:** Assoc. Prof. Celalettin TOPBAŞ  
University of Health Science

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**UNIVERSITY OF HEALTH SCIENCES  
HAMİDİYE CLINICAL RESEARCH ETHICS COMMITTEE  
INFORMED CONSENT FORM**

**Title of the Research Project:** Evaluation of the Effects of Different Intracanal Medicaments and Intracanal Cryotherapy on Endodontic Postoperative Pain in Teeth with Symptomatic Apical Periodontitis

**Principal Investigator:** Dr. Celalettin TOPBAŞ

**Other Investigators:** Assoc. Prof. Dursun Ali Şirin, Dr. Hüseyin Gürkan GÜNEÇ, Dt. Ali Osman İLHAN, Dt. Abdurrahman Kerim KUL, Dt. Büşra PEHLİVAN

You are invited to participate in a study titled “**Evaluation of the Effects of Different Intracanal Medicaments and Intracanal Cryotherapy on Endodontic Postoperative Pain in Teeth with Symptomatic Apical Periodontitis.**” You are invited because you have symptomatic apical periodontitis in one of your mandibular premolars. This study is conducted for research purposes and your participation is entirely voluntary.

Before deciding to participate, you will be informed about the study. After understanding the details and having your questions answered, if you agree to participate, you will be asked to sign this consent form. The study is conducted under the responsibility of Dr. Celalettin TOPBAŞ in the Department of Endodontics.

**Purpose of the Study & Number of Participants**

The study aims to compare the effects of intracanal medicaments and cryotherapy on postoperative pain following root canal treatment. The study will be conducted at a single center and will include a total of 80 participants.

**Participation**

Your participation is entirely voluntary. You may withdraw at any time without providing a reason, and your dental treatment will not be affected. The investigator may also remove you from the study if deemed in your best interest.

**What Will Happen if You Participate?**

During your first root canal treatment appointment, standard root canal therapy will be performed. At the end of the session, an intracanal medicament will be placed, and cryotherapy will be applied if assigned to that group. You will be asked to record your daily pain for 7 days using a provided form. Your second appointment will complete the root canal treatment. Your participation in the study lasts 7 days from the start of treatment. The overall research study duration is 6 months, which does not extend your clinical treatment period.

**Possible Risks and Discomforts**

No risks beyond those associated with routine root canal treatment are expected. Possible routine complications include:

- Anxiety, fainting, or syncope due to local anesthesia.
- Trismus (temporary difficulty opening the mouth).
- Pain or swelling at the injection site.
- Temporary facial paralysis, numbness, or muscle weakness due to anesthesia.
- Rare allergic reactions to anesthetic agents.
- Tissue injuries due to patient movement during the procedure.

**Potential Benefits**

Expected benefits include reduction or elimination of existing pain and healing of your tooth. The study may help identify methods that reduce postoperative pain after root canal treatment.

**Costs**

Participation does not involve any cost, nor will you receive payment for participation.

**Confidentiality**

Your personal information will be used for research and statistical analysis while remaining confidential. Only ethics committees or official authorities may access your information if necessary. Results may be published in scientific literature without revealing your identity.

**Participant Declaration**

I have read and understood the information about this research study. I voluntarily agree to participate without any pressure. I understand I may withdraw at any time without affecting my medical care. I understand the study will not incur any financial obligations on my part, and personal information will be kept confidential. In case of any health issue during the study, I will receive appropriate medical care without any cost. I have received explanations and have understood them. A copy of this signed consent form will be given to me.

**Participant**

Name, Surname: \_\_\_\_\_

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

Signature: \_\_\_\_\_