INFORMED CONSENT FORM

Official Title of the Study:

Evaluation of the Effect of Different Root Canal Disinfection Procedures on Postoperative Pain

ClinicalTrials.gov Identifier:

NCT number not yet assigned

Document Type:

Informed Consent Form

Ethics Committee:

Sivas Cumhuriyet University Clinical Research Ethics Committee

Document Date:

15 December 2022

Dear Participant,

The study you are invited to participate in is a scientific research study entitled “Evaluation of the Effect of Different Root Canal Disinfection Procedures on Postoperative Pain.” The aim of this study is to evaluate the effect of different root canal cleaning and disinfection procedures, particularly on postoperative pain following root canal treatment.

This study does not pose any additional risk or harm to you beyond routine clinical procedures. However, as with standard root canal treatment, potential complications such as instrument fracture within the root canal, root perforation, severe postoperative pain, or swelling may occur during or after the procedure.

Participation in this study is entirely voluntary. Before making your decision, we would like to provide you with detailed information about the study. If you decide to participate after reading and understanding this information, please sign this form.

To be eligible for inclusion in this study, you must be between 18 and 65 years of age, regardless of gender; the single-rooted tooth to be treated must not present with spontaneous pain or swelling; you must not have used analgesics within the last 12 hours or antibiotics within the last one week prior to the procedure. Female participants must not be pregnant or breastfeeding.

As a participant, you are expected to perform the requested pain assessments at the specified dates and times, respond accurately and appropriately to the investigator's questions, and deliver the results to the investigator in a timely manner.

If you agree to participate, you will be examined by Assoc. Prof. Demet ALTUNBAŞ or a dentist appointed by her, and your clinical findings will be recorded.

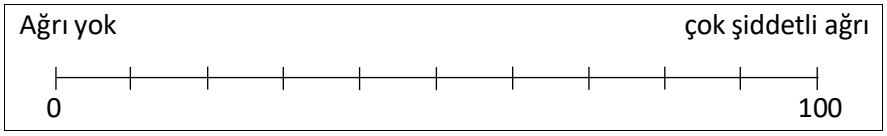
In this study, root canal treatment will be performed under local anesthesia with rubber dam isolation. Any existing caries will be removed, previous restorations will be eliminated, and the root canal will be mechanically prepared. Following preparation, the irrigation and disinfection protocol corresponding to the group to which you are randomly assigned—determined at the beginning of the study by a computer-generated randomization program—will be applied.

All procedures routinely performed during standard root canal treatment will also be applied to you. The irrigation and disinfection procedures used in this study are all intended to remove debris and microorganisms from the root canal system and provide similar therapeutic effects. However, due to factors such as higher cost, space requirements, limited practicality in high-patient-volume clinics, and longer application time, some adjunctive disinfection procedures are not routinely used despite their potential to offer more effective treatment.

Following completion of all disinfection procedures, the root canal will be obturated. After treatment, you will be asked to record the intensity of pain you experience at 6, 24, 48, and 72 hours, as well as on the 7th day, by marking the appropriate point on a 0–100 mm visual analog scale provided in the patient evaluation forms.

Routine follow-ups will be conducted for seven days through in-person clinical visits or telephone communication. At the end of one week, you will be asked to return to our clinic with

the completed pain assessment form for evaluation. A total of 80 volunteers will be included in this study, which will have a duration of 24 months.



If any new information arises during the study that may affect your willingness to continue participation, you or your legal representative will be informed immediately.

For additional information about the study or in case of any problems, adverse effects, or discomfort related to the study, you may contact the investigator Research Assistant Dentist İbrahim AKDENİZ at [redacted]

All examinations, tests, procedures, and medical care provided within the scope of this study will be free of charge. No fees will be requested from you or your social security institution. Any health problems arising directly or indirectly from the research procedures will be treated by the responsible investigator, and no financial burden will be imposed on you for medical interventions.

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time without any penalty or loss of benefits. The investigator may also withdraw you from the study if you fail to comply with the treatment protocol, disrupt the study schedule, or for reasons such as enhancing treatment efficacy.

The results of this study will be used for scientific purposes only. If you withdraw from the study or are withdrawn by the investigator, your medical data will not be used.

All your medical and personal identification information will be kept confidential. Even if the study is published, your identity will not be disclosed. However, study investigators, monitors, ethics committees, and authorized regulatory authorities may access your medical records when necessary. You have the right to access your own medical information upon request.

Consent to Participate

(This section will be handwritten by the volunteer.)

I have read and listened to the information provided above prior to the initiation of the study. I have asked the investigator all questions that came to mind, and I fully understand all written and verbal explanations given to me. I was given sufficient time to decide whether or not to participate in the study. Under these conditions, I authorize the study investigators to review, transfer, and process my medical data, and I voluntarily accept the invitation to participate in this study without any coercion or pressure.

A signed copy of this consent form will be provided to me.

Volunteer:

Name and Surname:

Address:

Telephone/Fax:

Date and Signature:

Investigator Providing Information:

Name and Surname:

Title:

Address:

Telephone/Fax:

Date and Signature:

Witness to the Consent Process:

Name and Surname:

Title:

Address:

Telephone/Fax:

Date and Signature: