INFORMED CONSENT FORM

Treatment outcomes of full pulpotomy using two different calcium silicate-based materials in mature permanent teeth with irreversible pulpitis symptoms: A randomized clinical trial

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Dear Volunteers,

We are requesting your permission to participate in our planned research titled " Treatment outcomes of full pulpotomy using two different calcium silicate-based materials in mature permanent teeth with irreversible pulpitis symptoms: A randomized clinical trial" to be conducted at our clinic. This study is conducted for research purposes. It is important for you to understand why and how the study is conducted, how the information related to the study will be used, what the study involves, its potential benefits, risks, and discomforts before making a decision to participate. Please take time to carefully read the information below and discuss it with your doctor. After you are fully informed about the study and your questions are answered, if you choose to participate, you will be asked to sign this form. We will also provide you with information about this study and obtain your permission to participate if you agree.

Objectives and Background of the Study, and How Many People Will Participate?

The purpose of the study is to evaluate the clinical success and effectiveness of two different dental filling materials in permanent teeth with symptoms of partial pulp inflammation. These biocompatible filling materials are applied when nerve tissue is exposed in teeth with deep decay. If the disease symptoms in permanent teeth with partial pulp inflammation are appropriate, these treatments can be applied to prevent unnecessary root canal treatments, thus preserving the vitality of the nerve tissue and consequently the health of the tissue. Preserving the vitality of the nerve tissue is of great importance due to its role in the defense mechanism of the nerve tissue and in maintaining the structural integrity of the tooth. This practice is routinely performed in Oral Dental Health Centers (ADSM), Oral Dental Health Center Hospitals (ADSH), and Faculties of Dentistry. The study will be conducted at a single center (Endodontics Department Clinic of Fırat University Faculty of Dentistry) and will require your continuation in the study for 12 months (1 treatment session, 4 control sessions) with 60 patients planned to be included.

Should I Participate in This Study?

Your participation in this study is entirely voluntary. If you agree to participate, this informed consent form will be given to you to sign. Even if you sign this form now, you have the right to withdraw from the study at any time you wish. If you choose not to participate or withdraw from the study, your doctor will apply the most appropriate treatment plan for you. Similarly, the doctor conducting the study may decide that it is not beneficial for you to continue in the study and can exclude you from the study with an explanation.

Are There Other Alternative Treatments Besides the Proposed Research Method?

The treatment method and material to be applied in the study are those used in routine live tooth treatments at the Fırat University Faculty of Dentistry Endodontics clinic, and the effectiveness of these materials will be

investigated. The proposed treatment method is a protective treatment method between filling treatment and root canal treatment. If you wish, instead of this treatment, root canal treatment can be applied to your tooth with routine materials used in the clinic.

What Can I Expect If I Participate in This Study?

The study period is set for 12 months. If you participate in this study; the necessary clinical examination will be performed, the decay in the tooth or teeth that meet the inclusion criteria for the study will be cleaned, the exposed nerve tissue will be partially removed, and the stages to be followed after placing the biocompatible filling material on the exposed nerve tissue are described below. All treatments will be performed by a single dentist (endodontics specialist). Diagnostic periapical (small) radiography will be taken before treatment, after treatment, and during control follow-ups. Additionally, images of the relevant teeth will be taken with a camera (your face will not appear, only intraoral photos) before treatment, during treatment, after treatment, and during control follow-ups. Local anesthesia will be used to numb the tooth and surrounding tissues. After removing the tooth's decay, the inflamed pulp of the tooth will be removed up to the clean part. Then a biocompatible covering material will be placed on the tooth surface, and permanent fillings will be made. The patient will be given routine recommendations and pain information after the treatment, and it will be requested to fill in the post-operative pain scale up to the 1st week after the treatment and note the drugs and doses used if any. After the first treatment session, control sessions will be held at 1 week (only for post-treatment pain assessment) and at 3-6-12 month periods (each control session is approximately 20-30 minutes). You will need to attend these sessions. During the controls, the necessary clinical examination will be performed, control radiographs will be taken, and the filling quality will be scored. Additionally, if pain or swelling is detected during the follow-up, a further treatment method, root canal treatment, will be applied to the monitored tooth.

What Do I Need to Do?

After the treatment with biocompatible filling material, you need to come to the controls at the specified dates and times at 1 week and 3-6-12 months. Besides, you need to perform your routine oral care.

What Are the Risks and Discomforts of the Study, and What Will Be Done in Case of Possible Harm You May See?

The materials to be used are normally approved by the Ministry of Health and routinely used in clinics, and they do not have a harmful effect on you. Nerve covering materials are applied to preserve the vitality of the exposed nerve tissue surface/surfaces, the defense mechanism of the nerve tissue, and the structural integrity of the tooth. Any pain, swelling, breakage of the filling or tooth, etc., that may occur after the applied treatment can also be seen in routine deep decayed tooth treatments. If you notice these situations, it will be checked if you contact us. If these situations are noticed during routine controls, root canal treatment will be done if appropriate for the relevant teeth, the participation of teeth that have root canal treatment in the study will end, but routine clinical follow-ups will continue with the patient's consent. No fee will be requested from you for these applications.

What Are the Benefits of Participating in This Study?

The treatment performed prevents the need for more invasive treatment, root canal treatment. Thanks to the control sessions, you will be able to go to the dentist 4 times for 1 year to have your teeth checked and ensure that your oral dental health is monitored. Therefore, since you will be under regular dentist control, early intervention can be made to possible cavities in your other teeth. Additionally, the data obtained from the research will be evaluated and will benefit the community.

What Will Happen If New Information Is Obtained About the Research?

If new information is obtained about the research subject, you will be informed in a timely manner. You have the right to withdraw from the research if you have any reservations that may affect your desire to continue participating in the research.

What Are the Situations or Reasons That May Require the Termination of Your Participation in the Study?

If you want to leave the study, you can leave without any responsibility. In cases of moving to a different city or country, In cases where you cannot come to control sessions, You can leave the research by informing the researchers.

What Is the Cost of Participating in This Study?

You will not incur any financial burden by participating in the study, and no payment will be made to you.

How Will the Security of Your Personal Information Be Ensured?

The doctor treating you in the research will use your personal information to conduct the research and necessary analyses. Your file and digital records will be kept in a locked cabinet and encrypted computer during the research and will not be shared. At the end of the research, you have the right to request information about this information. Research results and photos taken from teeth (excluding your face and personal information) may be published in medical literature at the end of the research, but your identity will definitely not be disclosed.

Inspectors, attendance takers, the Ethics Board, the Ministry of Health, and other relevant health authorities can directly access your original medical records. By signing this informed voluntary consent form, you will only grant access permission to the aforementioned persons and institutions. However, identity information will be kept confidential and will not be disclosed to the public.

For More Information, Assistance, and Contact, Whom Can I Contact?

If you have a problem related to your treatment or need additional information about the research, please contact the following person/people.

(Volunteer's Statement)

It has been stated by xxx that a medical research will be conducted, and the information above about this research has been communicated to me, and I have read the relevant text.

I have not encountered any coercive behavior regarding my participation in the research. I know that if I refuse to participate in the research, this will not harm my medical care and my relationship with the doctor. I can withdraw from the research during its conduct without giving any reason.

I will not incur any financial responsibility related to the expenses of the research, nor will I receive any payment.

Assurance has been provided that all necessary medical interventions will be available in case any health issues arise, whether directly or indirectly, from the research practices. I will not be financially liable for these medical interventions.

Should I encounter any health issues related to the research at any time, I am aware that I can call the physicians whose phone numbers are provided above. I have signed this form in duplicate, and a copy of this form has been given to me.

I have read all the explanations in the informed consent form. The research subject and objectives mentioned above were explained to me both in writing and verbally by the physician named below. I am aware that I am volunteering for this research and that I may withdraw from the study at any time, with or without reason.

I have fully understood all the explanations made to me. Under these conditions, I voluntarily consent to participate in the specified clinical research, without any coercion or pressure.

Name-Surname and Signature of Volunteer:

Name-Surname and Signature of Researcher: