INFORMED CONSENT FORM

Treatment outcomes of partial pulpotomy using two different calcium silicate materials in cariously exposed mature permanent teeth: A randomized clinical trial

NCT number: has not been created yet
Document Date;

Date of creation: 05.12.2023

Dear Volunteers,

We invite you to participate in the research study titled "Treatment outcomes of partial pulpotomy using two different calcium silicate materials in cariously exposed mature permanent teeth: A randomized clinical trial" planned at our clinic. This study is conducted for research purposes. Before deciding to participate, it is crucial to understand the reasons and methods of the research, how the information will be used, what the study entails, and its potential benefits, risks, and discomforts. Please take your time to read the information below carefully and discuss it with your doctor. After you are fully informed and all your questions are answered, if you wish to participate, you will be asked to sign this form. We will also provide you with detailed information about the study and obtain your consent to participate.

What are the objectives and basis of the study, and how many others will participate?

The aim of the study is to evaluate the clinical success and effectiveness of two different dental filling materials in treating mature permanent teeth with exposed pulps due to deep caries. These biocompatible filling materials are used when the nerve tissue is exposed in teeth with deep cavities. If clinical symptoms are suitable in deeply decayed permanent teeth, 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 crucial for maintaining the defense mechanism of the nerve and the structural integrity of the tooth. This procedure is routinely performed in individuals with deep cavities at Oral Dental Health Centers, Oral Dental Health Center Hospitals, and Faculties of Dentistry. The research will be conducted at a single center and will require your participation for 12 months (1 treatment session, 4 control sessions) with a total of 60 teeth (up to 60 patients) planned to be included in the study.

Should I participate in this research?

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

Are there alternative treatments available aside from the proposed study method?

The treatment method and materials used in the study are those typically used in living tooth treatments at the XXUniversity Faculty of Dentistry, Endodontics clinic, and their effectiveness will be evaluated. The suggested treatment method is a conservative approach between filling treatment and root canal therapy. If you prefer, root canal treatment can be performed on your tooth using routine materials used in the clinic instead of this treatment.

What should I expect if I participate in this research?

The duration of the research is set for 12 months. If you participate, after the necessary clinical examination, if your tooth or teeth meet the inclusion criteria, the decay will be removed, and a biocompatible filling material will be placed over the exposed clean nerve tissue. All treatments will be performed by a single clinician specializing in endodontics. Diagnostic periapical radiography of the relevant tooth will be taken before treatment, after treatment, and during follow-up sessions. High-quality images of the relevant teeth will also be taken before treatment, during treatment, after treatment, and during follow-up sessions (only intraoral photos, your face will not be shown). Local anesthesia will be used to numb the tooth and surrounding tissues. After removing the decay, the inflamed pulp of the tooth will be removed up to the clean portion. Then, a biocompatible capping material will be placed on the tooth surface, and permanent fillings will be made. Routine advice and pain information will be provided post-treatment, and you will be asked to fill out a postoperative pain scale for the first week after treatment and note any medications and their dosages if used. Follow-up sessions will be conducted at 1 week (only for pain assessment), 3 months, 6 months, and 12 months (each session will last approximately 20-30 minutes). You are required to attend these sessions. Necessary clinical examinations will be conducted during these sessions, control radiographs will be taken, and the quality of the filling will be scored. Additionally, if issues such as pain or swelling are detected during the follow-up, root canal treatment will be administered to the monitored tooth.

What do you need to do?

You are required to attend the follow-up sessions at 1 week, 3 months, 6 months, and 12 months as scheduled after the treatment with the biocompatible filling material. Additionally, you should maintain your routine oral care.

What are the risks and discomforts of the research, and what will be done in case of potential harm?

The materials used are normally approved by the Ministry of Health and routinely used in clinics, and they are not harmful to you. Nerve capping materials are applied to help preserve the vitality of the exposed nerve tissue surfaces, assist in the defense mechanism of the nerve tissue, and protect the structural integrity of the tooth. Potential adverse effects such as pain, swelling, or fracture of the filling or tooth that may occur post-treatment are also seen in routine treatments of deeply decayed teeth. If you notice these conditions, they will be checked upon your contact. If these conditions are observed during routine checks, and if appropriate, root canal treatment will be performed on the relevant teeth, ending their participation in the study, but routine clinical follow-ups will continue with the patient's consent. No fees will be charged for these procedures.

What are the benefits of your participation in this research?

The treatment prevents the need for more invasive treatments such as root canal therapy. Through the control sessions, you will have the opportunity to visit the dentist four times over a year to have your teeth checked, ensuring that you are monitored for good oral and dental health. Therefore, because you will be under regular dental control, early intervention can be made for potential decay in your other teeth. Additionally, the data obtained from the study will be evaluated and will benefit society.

What will happen if new information is obtained about the research?

If new information is obtained related to the research topic, you will be informed in a timely manner. If you have any concerns that may affect your desire to continue participating in the study, you have the right to withdraw from the research.

What situations or reasons will require the termination of your participation in the research?

You can withdraw from the research without any obligation if you wish to do so. If you move to a different city or country, or if you cannot attend the control sessions, you can withdraw from the research by informing the researchers.

What is the cost of participating in this research?

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

How will the security of your personal information be ensured?

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

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

For more information, help, and contact, whom can I approach?

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

(Volunteer's Declaration)

I have been informed that a medical research will be conducted by XXX and the above information related to 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, it will not harm my medical care or my relationship with the physician. I can withdraw from the research at any time during its conduct without providing any reason.

I am not under any financial obligation regarding the expenses related to the research. No payment will be made to me.

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: