Tilte: Comparison of Lesion Sterilization and Tissue Repair Technique With Conventional Pulpectomy in the Treatment of Pulpal Lesions in Primary Molars in Children

Unique Protocol ID : B.30.2.ATA.0.01.00/477

NCT Number : Not assigened yet

Date : August 1, 2024

Document Type: Consent Letter

TO BE PERFORMED IN PEDIATRIC PATIENTS
FOR RESEARCH
"PARENT" INFORMED CONSENT FORM

Title of the Research Project: Comparison of Lesion Sterilization and Tissue Repair Method with Traditional Pulpectomy in the Treatment of Pulpal Lesions of Primary Molars in Pediatric Patients.
Name of the Supervisor Investigator: Sera ŞİMŞEK DERELİOĞLU
Investigators' Name: Taymour ABUAWWAD
Supportive (if any): Atatürk University, BAP

Dear parents;

We ask for your permission for your child to take part in a study titled "Comparison of Lesion Sterilization and Tissue Repair Method with Traditional Pulpectomy in the Treatment of Pulpal Lesions of Primary Molars in Pediatric Patients", which will be carried out under the consultancy of Prof. Dr. Sera ŞİMŞEK DERELİOĞLU. Your child is invited to this study because he or she has suffered from pulpal lesions, tooth decay, tooth abscesses and/or pulpal infections. This study is conducted for research purposes and participation is voluntary. We want to inform you about the research before you decide whether your child should participate in the study. Once you are fully informed about the study and your questions have been answered, you will be asked to sign this form if you would like your child to participate. We will also inform your child about this research and ask him or her permission to participate in this study.

What are the aims and basis of the study, how many people other than my child will participate in this study?
Aims and Basis of the Study:
The aim of this study is to compare the Lesion Sterilization and Tissue Repair (LSTR) method and the traditional pulpectomy method in the treatment of infections in primary molars. The LSTR method is a minimally invasive approach to sterilize infected pulp tissue and repair the tissue with antibiotics. This study aims to evaluate the efficacy and safety of the LSTR method compared to traditional root canal treatment.

Why this study should be carried out in children:
Pulpal lesions and infections are common in children, causing pain and discomfort. Traditional endodontic treatment methods (root canal treatment) can hardly be applied in cases such as children's inability to cooperate, root resorption and insufficient bone support. The LSTR method, on the other hand, is a promising alternative treatment method for pediatric patients because it is simpler and shorter. Therefore, it is important to conduct the study in children in order to evaluate how effective this method is clinically and radiographically.

How many people are planned to be included in the study:
A total of 108 children are planned to be included in this study. Participants will be divided into two groups: 54 children will be treated with the LSTR method, and the other 54 children will be treated with the traditional root canal treatment method. In this way, the effectiveness of both treatment methods can be evaluated comparatively. The type of treatment to be performed will be decided according to the condition of the child's tooth.

Should my child participate in this study?
Whether or not your child takes part in this study is entirely up to you. If you allow yourself to participate, this written informed consent form will be given to you for signature. Even if you sign this form now, you can withdraw your child from working at any time. If you do not want him to participate or if you leave the study, your doctor will apply the most appropriate treatment plan for your child. Likewise, the doctor conducting the study may decide that it would not be beneficial for your child to continue studying and may exclude him from the study.

What awaits my child if he/she participates in this study?
Within the scope of this research, your child will not be treated with any intervention other than the routine procedures for his treatment. The study will be carried out only within the framework of routine dental procedures that have already been performed during its treatment. Procedures to be performed during the treatment of your child's pulpal lesions will include routine root canal treatment or LSTR treatments. The duration of your child's stay in this study is considered to be 1 year.
What are the risks and inconveniences of working, what will be done in case of possible harm to my child?

1. Complications such as recurrence of infection (this risk also exists when left untreated), allergic reactions (to antibiotics) or treatment failure may occur in teeth treated with the LSTR method. There are similar risks in root canal treatment. Although rare, undesirable conditions such as infection, pain and swelling may develop in both treatment methods.
2. In case of possible harm to your child due to the research, all necessary medical attention will be provided by us; All expenses in this regard will also be undertaken by us. In addition, in any situation that endangers your child's health, treatment will be terminated immediately and alternative treatment options will be offered.

What are the benefits of my child taking part in this study?
Although there is no direct health benefit for your child to take part in this study, your child will be closely monitored during the treatment process and necessary medical interventions will be made when necessary. The data from the study could contribute to improving treatment options for other children with similar conditions in the future. The LSTR method can be an important step in protecting children's dental health and avoiding tooth extractions by offering a simpler and less time-consuming treatment as an alternative to root canal treatment. As a public benefit, this research can contribute to the development of more effective treatment methods in the field of pediatric dental health and to the improvement of existing treatment protocols.

How much does it cost for my child to participate in this study?
You will not be financially burdened by participating in the study, and you will not be paid anything.

How will my child's personal information be used?
Your study doctor will use personal information about your child to conduct research and statistical analysis, but your child's identity will be kept confidential. Only if necessary, ethics committees or official authorities can review information about your child. At the end of the study, you have the right to request information about the results. Study results may be published in the medical literature, but your child's identity will not be disclosed.

Who can I contact for more information, help and contact?
If you have a problem with the study or need additional information about the study, please contact the person below.
NAME : Taymour Abuawwad
POSITION: Ph.D. student
PHONE : +905441373912

(Statement of the parent of the participating child)

In the Department of Pedodontics at Atatürk University, Dr. Taymour Abuawwad stated that a medical research would be carried out, and the above information about this research was conveyed to me and I read the relevant text.
I have not encountered any coercive behavior about my child's participation in the study. I also know that if I refuse to allow my child to participate in the study, it will not harm my child's medical care or my relationship with the doctor. During the conduct of the study, I can withdraw my child from the research without giving any reason.
I do not assume any monetary responsibility for research expenses. I won't be paid either.
In case of any health problem that may arise due to the research practice, whether direct or indirect, the necessary assurance was given that all kinds of medical intervention would be provided. (I'm not going to be financially burdened with these medical interventions either).
When we encounter a health problem during the research; I know that I can call Dr. Taymour Abuawwad at +905441373912 at any time, and he can reach me from Atatürk University Faculty of Dentistry Pediatric Department Erzurum/Yakutiye. (Doctor's name, telephone and address information must be specified)
I have understood in detail all the explanations that have been given to me. Under these circumstances, I voluntarily agree for my child to participate in the clinical trial in question.

A copy of this signed form paper will be given to me.

DATE:

Parent's name and surname:

Parent's signature: DATE:

Name-surname, title of the researcher :
Address:
Wire: Signature: