28.08.2023

Informed Consent Form

Researcher's/Doctor's Statement

We are planning to conduct scientific research to compare the anesthesia administered by the traditional method with the computer-controlled anesthesia device Sleeper One, and to evaluate the pain and anxiety caused by both methods during the treatment of permanent teeth with molar incisor hypomineralization. The name of the planned research is "**Evaluation of the Effects of Computer-Controlled and Traditional Local Anesthesia on Pain and Anxiety in Children with Molar Incisor Hypomineralization.**"

We are inviting you to participate in this study on patients with molar incisor hypomineralization (MIH) and/or patients who visit our clinic for routine check-ups, as your medical condition meets these conditions. However, it should be noted that participation in the study is voluntary. You must decide to participate in this scientific study of your own free will. No one can suggest or pressure you while making this decision.

Before you make your decision, we would like to inform you about this scientific study and the procedures to be followed if you agree to take part in this study. After reading and understanding this information, please sign the form if you wish to participate in this scientific research.

Information about the scientific study

You are invited to participate in the study because you are an individual aged 6-12 years, without systemic disease, with permanent upper and lower first molars with MIH and deep dentin caries. This study will be conducted at Tokat Gaziosmanpaşa University, Faculty of Dentistry, Department of Pediatric Dentistry. The teeth of 28 patients with MIH included in the study will be randomly divided into two groups. One group will receive intraosseous anesthesia with traditional injection and the other group will receive intraosseous anesthesia with a computer-controlled anesthesia device (Sleeper One).

For patients who meet the inclusion criteria, the procedures will be performed by the same physician in a single-unit room. Patients will be given an appointment to be the first patient in the morning (08.15). Patients will be asked to come with a full stomach and brushed teeth. All procedures to be performed before the application will be explained using the tell-show-apply technique.

Patients included in the control group; local anesthesia will be applied with a conventional syringe.

The study group will receive local anesthesia using Sleeper One in accordance with the manufacturer's instructions.

In all patients, 15 minutes before anesthesia, 15 minutes after anesthesia and at the end of treatment, the mouth will be rinsed with water and patients will be asked to spit into the saliva collection container. Since cortisol will be measured from the saliva collected, water will be used as rinsing solution to prevent the hormone level from being affected by anesthesia or chemicals in the mouth.

The pulse rate of the patients will be measured with a finger-type pulse oximeter device. With the device attached to the right index finger, three blood pressure values will be obtained before, after and after anesthesia and the values will be recorded on the case follow-up form.

A pulse oximeter will be attached to the index fingers of the right hand of the patients and three values will be obtained before anesthesia, after anesthesia and after the procedure and the values will be recorded on the case follow-up form.

All patients before, after anesthesia and after treatment to measure pain level for each session;

- Visual Analogue Scale (VAS)
- Wong-Baker FACES Pain Rating Scale (WBS)
- Face, Legs, Activity, Cry, Consolability Scale (FLACC) will be applied and added to the records.

Participant (Volunteer)

Address : *Date:*
Phone number :
Signature :

Interview Witness

Name, Surname :
Address :
Phone number :
Signature :

Katılımcı (Gönüllü) ile Görüşen Araştırmacı

Name, Surname *: Associate Professor Canan Bayraktar Nahir and Assistant Professor Necibe Damla ŞAHİN*
Adres *: Tokat Gaziosmanpaşa University Faculty of Dentistry Department of Pediatric Dentistry*

All patients will be administered the Children's Fear Survey Schedule- Dental Subscale (CFSS-DS) scale to determine anxiety levels before anesthesia for each session.

The anesthesia device to be used in this study, Sleeper One, which has recently become widely used, is a computer-controlled local anesthesia device with a permanent resistance system that regulates injection based on tissue density. This device, which has been studied many times before, minimizes the pain during anesthesia, especially in pediatric patients. At the same time, it creates deeper anesthesia and promises hope especially in patients with anesthesia problems such as MIH.

The aim of this study is to compare the effect of traditional anesthesia method and computer-controlled anesthesia method on pain and anxiety. In this way, the success of Sleeper One will be investigated and therefore the success of the treatment of teeth with MIH will be improved.

Conditions to be known within the scope of the study and rules to be followed by researchers and volunteers

In case you participate in research;

1. You will not be charged any fee.
2. You will not receive any additional payment for taking part in the study.
3. The confidentiality of your information, which must remain between you and the physician, will be treated with the utmost care and respect.
4. Your personal information will be protected with the utmost sensitivity during the use of research results for educational and scientific purposes.
5. Researchers are responsible for any health and other problems that may occur during the study.
6. You can leave the study at any stage of the voluntary participation. However, it is important that you inform the researchers before you leave.
7. If you do not agree to participate in the study, there will be no change in your treatment and clinical follow-up, and the treatment of your disease will continue with the same care and attention as always.
8. Your child will be informed about this research in a way that he/she understands and his/her consent will be obtained for participation in the study.

Declaration of the Participant (Volunteer) / Patient

Associate Professor Canan Bayraktar Nahir and Assistant Professor Necibe Damla ŞAHİN stated that research would be conducted in Tokat Gaziosmanpaşa University Faculty of Dentistry, Department of Pediatric Dentistry, and the above information about this research was conveyed to me. After this information, I was invited as a "participant" to such research.

If I participate in this research, it has been clearly and explicitly stated that the confidentiality of my personal information, which must remain between me and the physician, will be treated with the utmost care and respect during this research, and that my personal information will be carefully protected during the use of the research results for educational and scientific purposes.

I do not assume any financial responsibility for the expenses to be incurred for the research. It has been clearly and unequivocally stated that I will not be charged any fees and I will not be paid anything.

During the execution of the project, I was informed that I have the right to withdraw from the research without giving any reason. However, I am also aware that it would be appropriate to inform the researchers in advance

Participant (Volunteer)

Address : *Date:*
Phone number :
Signature :

Interview Witness

Name, Surname :
Address :
Phone number :
Signature :

Katılımcı (Gönüllü) ile Görüşen Araştırmacı

Name, Surname *: Associate Professor Canan Bayraktar Nahir and Assistant Professor Necibe Damla ŞAHİN*
Adres *: Tokat Gaziosmanpaşa University Faculty of Dentistry Department of Pediatric Dentistry*

that I will withdraw from the research in order not to leave them in a difficult situation. I may also be excluded from the study by the researcher provided that no harm is caused to my medical condition.

In case of any health-related negativities that may arise during the research process, whether direct or indirect, the responsibility belongs to the researchers and I will not be under any financial burden.

If I encounter a research-related health problem during the research, I know that I can consult Associate Professor Canan Bayraktar Nahir and Dr. Necibe Damla ŞAHİN at any time of the day by calling +90 535 547 76 99 and +90 505 750 52 47.

I do not have to participate in this research and I can choose not to participate. I have not been subjected to any coercive behavior in order to participate in the study. I understand that if I refuse to participate, this will not harm my medical care and my relationship with the physician.

I have understood all the explanations given to me in detail. After a period of reflection on my own, I have made the decision to take part in this research project as a "participant" (volunteer) of my own free will. I accept the invitation with great pleasure and willingness.

Participant (Volunteer)

Address : *Date:*
Phone number :
Signature :

Interview Witness

Name, Surname :
Address :
Phone number :
Signature :

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