PARENT/GUARDIAN INFORMED CONSENT FORM FOR SCHOOL-AGED CHILD PARTICIPANTS

Research Project Title:	Comparison of the Effects of Transcutaneous Electrical Nerve Stimulation and Low-Level Laser Therapy in Non-Invasive Orthodontic Pain Control
Principal Investigator:	Assist. Prof. Ersin YILDIRIM
Other Researcher(s):	Dentist Neslihan BÖLENLER
Sponsor (if applicable):	

Dear Parents/Guardians,

We are asking for your permission for your child to take part in a study entitled “Comparison of the Effects of Transcutaneous Electrical Nerve Stimulation and Low-Level Laser Therapy in Non-Invasive Orthodontic Pain Control,” which is planned to be conducted at our clinic. Your child has been invited because they require orthodontic treatment. This study is being conducted for research purposes, and participation is voluntary. Before you decide whether your child should take part, we would like to inform you about the study. After you have received complete information 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 explain this study to your child and ask for their agreement to take part.

What are the aims and rationale of the study, and how many children will take part?

Patients may experience pain during orthodontic treatment. The literature reports that orthodontic pain is more common among adolescents and pre-adolescent children. Studies have shown that some individuals discontinue treatment because of orthodontic pain, while others have difficulty adapting to the process, which prolongs treatment. Our study will compare the effectiveness of transcutaneous electrical nerve stimulation and low-level laser therapy - two methods for controlling pain during orthodontic treatment that have no side effects for the patient - in reducing orthodontic pain. This is a single-centre study planned to include a total of 72 participants.

Should my child take part in this study?

Whether your child takes part is entirely up to you. If you give permission, you will be given this written informed consent form to sign. Even after signing, you may withdraw your child from the study at any time. If you do not want your child to take part, or if you withdraw them, the doctor will provide the treatment plan considered most suitable for your child. Likewise, the study doctor may decide that continued participation is not beneficial and may withdraw your child from the study.

What will happen to my child if they take part?

No procedures other than the routine procedures required for your child's orthodontic treatment will be performed within the scope of this study. The study will be conducted only by applying transcutaneous electrical nerve stimulation and low-level laser therapy, two comfortable, non-invasive methods with no side effects for your child, to reduce pain after treatment. Your child's participation in the study is expected to last 5 weeks.

What are the risks and discomforts of the study, and what will be done if my child is harmed?

1 For transcutaneous electrical nerve stimulation, low electrical energy will be delivered through pads placed on your child's skin. Other than mild tingling, your child will not experience any other pain or discomfort during this period.

2 During low-level laser therapy applied to the soft tissues inside your child's mouth, your child will not experience any pain or discomfort other than a mild warming sensation.

3 If your child experiences any harm as a result of the study, we will provide all necessary medical treatment and cover all related costs.

What are the possible benefits of my child's participation?

Reducing and controlling orthodontic pain affects the success of orthodontic treatment because it improves patient adherence. By comparing two non-invasive pain-relief methods, our study will help address the reported lack of research on transcutaneous electrical nerve stimulation and low-level laser therapy. It will establish the role of transcutaneous electrical nerve stimulation devices in reducing orthodontic pain and evaluate their future clinical use. These devices are easy to apply, inexpensive and comfortable; models have even been developed for home use, although their use in orthodontic pain control is not yet widespread. The literature also indicates that more clinical studies are needed to standardise the parameters used for pain control with low-level laser therapy. Our study will also contribute to scientific knowledge in this respect.

What will my child's participation cost?

You will not incur any financial burden as a result of participation, and no payment will be made to you.

How will my child's personal information be used?

The study doctor will use your child's personal information to conduct the research and statistical analyses, but your child's identity will be kept confidential. Ethics committees or public authorities may review information about your child only when necessary. At the end of the study, you have the right to request information about the results. The study results may be published in the medical literature, but your child's identity will not be disclosed.

Whom can I contact for more information, assistance or questions?

If you have a problem related to the study or need additional information, please contact the person below.

NAME: Dentist Neslihan BÖLENLER
ROLE: Co-investigator, Dentist
TELEPHONE: 05426641954

STATEMENT OF THE PARENT/GUARDIAN OF THE CHILD PARTICIPANT

I was informed that Dentist Neslihan BÖLENLER would conduct medical research at the Department of Orthodontics, Hamidiye Faculty of Dentistry, University of Health Sciences. The information above was explained to me, and I have read the relevant text.

I have not been subjected to any coercion regarding my child's participation. I understand that refusing participation will not adversely affect my child's orthodontic treatment or my relationship with the doctor. I may withdraw my child from the study at any time without giving a reason.

I will not bear any financial responsibility for study-related expenses, and no payment will be made to me.

I have been given the necessary assurance that, should any health problem arise directly or indirectly from the study procedures, all necessary medical treatment will be provided. I will not incur any financial burden for such treatment.

If my child experiences a health problem during the study, I understand that I may contact Dentist Neslihan BÖLENLER at 05426641954 at any time, or contact University of Health Sciences, Sultan 2. Abdülhamid Han Training and Research Hospital, Orthodontics Clinic, Selimiye, Tıbbiye Cd., 34668 Üsküdar/Istanbul.

I have understood all the explanations given to me in detail. Under these conditions, I voluntarily consent to my child's participation in this clinical study.

I will be given a copy of this signed form.

Date: _____

Parent/guardian's full name: _____

Parent/guardian's signature: _____

Researcher's name and title: Dentist Neslihan BÖLENLER

Address: University of Health Sciences, Sultan 2. Abdülhamid Han Training and Research Hospital, Orthodontics Clinic, Selimiye, Tıbbiye Cd., 34668 Üsküdar/Istanbul

Telephone: 05426641954

Signature: _____

Date: _____

Note: The information section and the participant's statement must follow one another continuously and appear on the same page.