INFORMED CONSENT FORM

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):

You are invited 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.” You have been invited because you require orthodontic treatment. This study is being conducted for research purposes, and participation is voluntary. Before you decide whether to 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 wish to participate. This research is being conducted at the Department of Orthodontics, University of Health Sciences, under the responsibility of Assist. Prof. Ersin YILDIRIM.

What is the purpose of the study, and how many other people will take part?

Patients may experience pain during orthodontic treatment. 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 I take part in this study?

Whether you take part is entirely up to you. Even if you sign this form now, you are free to leave the study at any time without giving a reason. If you do not wish to take part or if you withdraw, your doctor will provide the treatment plan considered most suitable for you. Likewise, the study doctor may decide that continued participation is not beneficial and may withdraw you from the study; in that event, the most appropriate treatment will be selected for you.

What will happen to me if I take part?

No procedures other than the routine procedures required for your 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 that will have no side effects for you, to reduce pain after treatment. Your participation in this study is expected to last 5 weeks.

What are the risks and discomforts of the study?

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

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

3 If you experience 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 taking part?

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 it cost me to take part?

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

How will my personal information be used?

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

Whom can I contact for more information?

If you need additional information about the study, please contact the person below.

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

STATEMENT OF THE PARTICIPANT/PATIENT

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. After receiving this information, I was invited to take part in the study as a participant.

I have not been subjected to any coercion regarding participation. I understand that refusing to take part will not adversely affect my orthodontic treatment or my relationship with the doctor. I may withdraw from the study at any time without giving a reason. However, I understand that it would be appropriate to inform the researchers in advance so as not to place them in a difficult position. I may also be withdrawn by the researcher, provided that this does not cause any harm to my medical condition.

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

I understand that the confidentiality of my personal information obtained through the study will be protected.

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

If I experience 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 freely and voluntarily agree to take part in this clinical study, without pressure or coercion.

I will be given a copy of this signed form.

Participant
Full name: _____
Address: _____
Telephone: _____
Signature: _____
Date: _____

Witness to the discussion
Full name: _____
Address: _____
Telephone: _____
Signature: _____
Date: _____

Physician who conducted the consent discussion

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.