Protocol Title: Motor Evoked Potential and Cortical Silent Period in Migraine

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INFORMED VOLUNTARY CONSENT FORM

Dear Volunteer Candidate,

We invite you to participate in the research titled "Investigation of Motor Evoked Potentials and Cortical Silent Periods in Migraine Patients" conducted at Istanbul Gelişim University. Before deciding whether to participate in this research, you should understand the purpose and method of the research, the potential benefits, risks, and discomforts it may pose to volunteers, and make your decision freely within the framework of this information. Therefore, it is crucial that you read and understand this form. This form contains the written form of the information provided to you verbally by us, the research directors. Before signing the form, please take the time to carefully read the following information, which was also provided to you verbally. If you wish, please discuss this information with your family, relatives, and/or doctor. If there is anything you do not understand, is unclear, or if you would like further information, please ask us. If you agree to participate, you will receive a copy of this form, signed by you and the witness present during the information session, for you to keep.

Participation in the research is entirely voluntary. You have the right not to participate in the study or to withdraw from the study at any time after participation. In either case, you will not be subject to any penalties or loss of rights.

Research Supervisor
(Prof. Dr. Kemal Sıtkı Türker)

This "Informed Consent Form" consists of two sections;

1) **INFORMATION**
2) **CONSENT**

PART 1: INFORMATION

1. Research Title:

Investigation of Motor Evoked Potentials and Cortical Silence Periods in Migraine Patients

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2. The Research is a Scientific Study

This study is designed to evaluate the excitability and inhibitory control levels of the motor cortex in migraine patients. It is not intended as a clinical treatment or to develop a commercial product.

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3. Purpose of the Research

The purpose is to analyze motor responses (MEPs) and cortical silence periods (CSPs) obtained from the motor cortex using Transcranial Magnetic Stimulation (TMS), and to evaluate signals at the motor unit level using needle EMG**.**

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4. Research Duration

Your participation in the research consists of a single session. The application duration is approximately 1–2 hours.

5. Number of Participants

A total of 40 volunteers are planned to participate in this study.

6–8. Methods and Process to be Applied in the Study

WHAT WILL BE APPLIED?

• The study will be conducted at the Translational Dentistry Research Laboratory of Istanbul Gelişim University, Faculty of Dentistry.

• Muscle contraction is controlled by the brain. When you decide to contract a muscle, an electrical signal is sent from the brain's nerve cells along the spinal cord to the muscle via motor nerves, causing the contraction. The contraction movement is adjusted and regulated by reflexes.

• For skin recording, the skin will be cleaned with 70% alcohol, lightly rubbed with abrasive gel, and surface electrodes will be attached to the skin, aligned parallel to the muscle fibers.

• For intramuscular recordings, the skin will be swabbed with 70% alcohol, and electrode wires will be inserted into the muscle using a 25G syringe needle. This needle will then be withdrawn, leaving the wires inside the muscle. You will be asked to contract the muscle several times. The inserted wires do not cause pain during the experiment and can be easily removed without pain at the end. The electrodes are sterile and disposable.

• During the recording, you will be asked to contract your muscles to the desired degree while looking at the screen in front of you.

• In each experiment, only one area of your body will be stimulated, and recordings will be taken from one or two muscles in that area. Electrical stimulation will consist of approximately 300 pulses at 1-3 second intervals, while transcranial brain stimulation will consist of approximately 300 pulses at 4-6 second intervals.

• The experiments will last a maximum of two hours, including preparation. Transcranial Magnetic Stimulation

o Transcranial magnetic stimulation (TMS) is a method used to investigate brain-muscle pathways by painlessly and noninvasively stimulating the brain.

o In this experiment, you will participate in, the effects of magnetic stimulation applied to the motor cortex on muscle movement and quiescence will be examined.

o During stimulation, you may feel contraction or twitching in certain muscles. The interval between pulses is at the nearest four seconds, and the magnetic stimulation administered individually (single pulses) is painless and harmless.

o The magnetic coils are a classic figure-of-eight with dimensions of 15 x 8 x 1 cm; the round coil is 13 cm in diameter and 2 cm thick**.**

9. Experimental Aspects of the Research

Because this study is for research purposes, it will not benefit you in any way. However, because it will identify nerve pathways in humans, it will provide a scientific basis for improving the clinical diagnosis and treatment of muscular and neurological diseases in the future. This method will allow the identification of nerve maps (neural electrical circuits) by examining the potentials generated in muscles by stimulation in humans. With this new method, these circuits will be redrawn without error, ensuring its safe use in clinical neurology.

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10. Possible Risks or Discomforts

• Mild muscle twitching, temporary headache, or a feeling of pressure on the scalp may occur during TMS application.

• A brief stinging sensation may occur during needle EMG.

• These effects are generally mild and temporary.

• Because we adhere to sterility regulations at needle insertion sites, no skin infections have been observed in our 30 years of practice. However, this is a possibility and is disclosed in the ethics committee applications. If a skin infection is encountered, we will clean the area with antiseptic (batticon), apply antibiotic ointment (furacin), and monitor its development**.**

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11. Clinical Benefit

This study will not have any direct therapeutic benefit for you. However, it is expected to contribute to the understanding of the neurophysiological basis of migraine**.**

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12. Alternative Approaches

If you do not wish to participate in the study, no action will be taken. You are not obligated to undergo these assessments.

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13. Compensation or Treatment

No medical harm is anticipated in the study. Volunteers will not receive any additional treatment or compensation.

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14. Payment Information

No fee or payment will be made for participation**.**

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15. Volunteer Responsibilities

• Arrive on time for appointments

• Follow instructions

• Be honest and open during the study

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16. Participation is Voluntary

Participation in the study is completely voluntary. You may withdraw from the study at any time without giving a reason. You will not lose any rights in this situation.

17–18. Confidentiality and Access

All your data will be kept confidential and accessed only by the research team. Your identity will remain confidential even if the research results are published. The ethics committee and relevant supervisory authorities can view the original records.

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19. Notification of New Information

You will be promptly notified of any new information that arises during the research process.

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20. Contact Information

You can contact us with any questions you may have:
Prof. Dr. Kemal Sıtkı Türker
Phone: +90 532 598 77 91
E-mail: ksturker@gelisim.edu.tr

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21. Withdrawal from the Study

During the study, the research team may decide to discontinue the study in cases such as technical inadequacy, your request, or cessation of eligibility for the study.

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22. Post-Study Application

The data obtained at the end of the study will be used for scientific purposes only; no treatment will be administered.

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23. Biological Material Information

Biological material (blood, tissue, etc.) will not be collected in this study**.**

SECTION 2: CONSENT / APPROVAL / CONSENT

I have read the information section regarding the research whose subject and purpose are specified above and have been informed, first verbally and then in writing, by the undersigned. I fully understand the scope and purpose of the study in which I am asked to participate, and my responsibilities as a volunteer. I have had the opportunity to ask and discuss the study and have received satisfactory answers. The potential risks and benefits of the study have also been explained to me verbally. I understand that my participation in the study is voluntary, that I can withdraw from the study at any time, with or without justification, and that I can be excluded from the study by the researcher regardless of my wishes, and that my current treatment will not be adversely affected by my withdrawal from the study.

Under these conditions:

1) I agree to participate in this Clinical Trial (my child's/guardian's participation in this study) voluntarily, without any pressure or coercion.

2) I consent to the individuals/institutions specified in the legislation accessing my personal information if necessary.
3) I consent to the information obtained in the study (on the condition that my identity remains confidential) being used for publication, archiving, and, if necessary, for transfer outside our country for scientific contribution.

I consent to participate in this clinical trial without any further explanation, without being under any pressure, and with full knowledge.

VOLUNTEER'S		**SIGNATURE**
NAME & SURNAME		
ADDRESS		
TEL. & FAKS		
DATE		

SIGNATURE OF THE RESEARCHER WHO MADE THE STATEMENTS		SIGNATURE
NAME &SURNAME		
DATE		
SIGNATURE OF THE ORGANIZATION OFFICIAL WHO WITNESSED THE CONSENT PROCESS FROM BEGINNING TO END		SIGNATURE
NAME &SURNAME		
POSITION		
DATE		

If the volunteer has a language/communication problem:

I translated all the explanations given to the volunteer by ….. I read and translated all pages of this form, which consists of … pages in total, including the information and consent sections. The information I translated was understood and approved by the volunteer.

TRANSLATOR'S SIGNATURE		SIGNATURE
NAME &SURNAME		
ADDRESS		
TEL. & FAKS		
DATE		

VOLUNTEER'S		SIGNATURE
NAME &SURNAME		
ADDRESS		
TEL. & FAKS		
DATE		

I have explained the purpose, content, method, benefits and risks of the study, and the volunteer's rights to the volunteer listed above. The patient's questions have been answered. Furthermore, the volunteer/legal representative has been asked to review this form in detail and sign it.

Person Providing the Explanations
Name and Surname:
Signature:
Date (day/month/year):…/…./…..

This Informed Consent Form, consisting of 7 pages, was prepared in two copies, and one copy was delivered to the patient/relative.