A PROSPECTIVE OBSERVATIONAL STUDY OF SUICIDAL IDEATION AND TREATMENT RESPONSE IN PSYCHIATRIC PATIENTS RECEIVING ELECTROCONVULSIVE THERAPY

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PAMUKKALE UNIVERSITY
NON-INTERVENTIONAL CLINICAL RESEARCH ETHICS COMMITTEE
INFORMED VOLUNTARY CONSENT FORM

You are invited to participate in a study titled "A Prospective Observational Study of Suicidal Ideation, Dissociative Symptoms, and Treatment Response in Psychiatric Patients Receiving Electroconvulsive Therapy." This study is being conducted for research purposes, and we encourage your participation. Participation in this study is entirely voluntary. Before deciding whether to participate, it is important that you understand the purpose of the study, how it is conducted, how your personal information will be used, and what the study involves. Please read the following information carefully and feel free to ask questions. After you are fully informed and your questions have been answered, you will be asked to sign this form if you wish to participate.

What are the aims and rationale of the study, and how many other people will participate?

This study aims to observationally evaluate the effects of ketamine+propofol and propofol anesthetic agents — used in routine clinical practice during Electroconvulsive Therapy (ECT) — on depression severity, suicidal ideation, and dissociative symptoms. The selection of the anesthetic agent will be made based on clinical judgment; the researchers will not intervene in this process and will only conduct observational assessments.

A total of approximately 65 volunteer patients will be included in the study. This research has been planned based on previously conducted similar studies, and it aims to contribute to the scientific literature with the data obtained. The estimated duration of the study is approximately 2 years.

Should I participate in this study?

Whether or not you participate in this study is entirely your decision. If you decide to participate, you will be given this written informed consent form to sign. Even if you sign this form now, you are free to withdraw from the study at any time and for any reason without explanation. If you choose not to participate or withdraw from the study, there will be no change in the medical care provided to you by your physician. You also have the right to withdraw your consent at any stage of the study.

What will happen if I participate in this study?

If you participate in this study, you will receive treatment with the anesthetic agent (Ketamine+Propofol or Propofol) determined as part of your Electroconvulsive Therapy (ECT) treatment. The following stages will take place during the study:

- Enrollment: Patients diagnosed with major depressive disorder or bipolar depression according to DSM-5 diagnostic criteria and scheduled to receive ECT treatment will be included in the study.
- Assessment Process: Three separate assessments will be conducted during the study:
    - Pre-ECT Assessment: Patients will be administered the Montgomery and Åsberg Depression Rating Scale (MADRS), the Beck Suicidal Ideation Scale, and the CADSS scale.
    - Post-ECT Assessment: After the completion of treatment, the same scales will be re-administered to analyze changes.

Participating in the research does not pose any additional risk beyond the natural course of your current treatment process. Your participation is entirely voluntary, and you may withdraw from the study at any time.

What are the benefits of participating in this study?

This study aims to better understand the effects of ketamine and propofol use in patients with depression and bipolar depression. Your participation may not provide direct personal benefit; however, the data obtained will contribute to the treatment of future patients in similar situations.

What is the cost of participating in this study?

You will not incur any financial burden by participating in the study, and no payment will be made to you.

How will my personal information be used?

Your researcher will use your personal information to conduct the research and statistical analyses. Your identifying information will be kept confidential by your researcher throughout the study. At the end of the study, you have the right to request information about the research findings. Without your written permission, your personal information cannot be viewed or disclosed by anyone else. The study results may be used in scientific publications upon completion of the study; however, your identity will not be disclosed.

Who can I contact for more information, assistance, or communication?

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

- Name: Nurdan Sağbaş
- Title: Research Assistant, M.D.
- Phone: Extension 4600

(Volunteer/Patient Declaration)

I was informed that a medical research study would be conducted at Pamukkale University Department of Psychiatry by Dr. Nurdan Sağbaş, and the above information regarding this research was conveyed to me. I have read the relevant text. Following this information, I was invited to participate in this research as a "participant."

I fully understand all the explanations provided to me in detail. Under these conditions, I voluntarily agree to participate in this clinical research of my own free will, without any pressure or coercion.

a. I was informed that I have the right to refuse to participate in the research. I also know that this will not cause any harm to my medical care or my relationship with my physician.

b. I am aware that I may withdraw from this study at any time without giving any reason, provided that I notify the responsible researcher/physician. I know that refusing to participate in this study or withdrawing later will not place me under any obligation, and that this will not in any way affect the medical care I may need now or in the future. (However, I am aware that it would be appropriate to notify the researchers in advance if I intend to withdraw, so as not to put them in a difficult position.)

c. The researcher/physician conducting the study may remove me from the study without my consent, provided that no harm is caused to my medical condition due to my negligence in fulfilling the requirements of the study protocol.

d. The results of the study may be presented at scientific meetings or publications. However, in such cases, my identity will be kept strictly confidential.

e. I do not assume any financial responsibility for the expenses related to the research. No payment will be made to me either.

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

Participant

- Name and Surname:
- Address:
- Phone:
- Signature:
- Date: