ClinicalTrials.gov Cover Page

Official Title: The Relationship of EEG Microstate Parameters and Neuroinflammatory Biomarkers With Treatment Response in Patients With Treatment-Resistant Major Depressive Disorder Receiving Electroconvulsive Therapy

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NOTE: The uploaded informed consent document requires full professional translation before inclusion. This placeholder cover page has been generated with the updated study dates.

Informed Consent Form for Patients and Healthy Volunteers Participating in a Research Study

Dear Participant,

You are invited to participate in a research study conducted by the Department of Psychiatry, Cerrahpaşa Faculty of Medicine, Istanbul University-Cerrahpaşa. Participation in this study is entirely voluntary. Before you decide whether to participate, we would like to provide you with information about the study. Please read the following information carefully. If you fully understand the information provided and agree to participate, please sign this informed consent form.

Study Title

The Relationship of EEG Microstate Parameters and Neuroinflammatory Biomarkers With Treatment Response in Patients With Treatment-Resistant Major Depressive Disorder Receiving Electroconvulsive Therapy

Approximately one billion people worldwide are affected by mental disorders, among which Major Depressive Disorder (MDD) is one of the most prevalent. Characterized by symptoms such as persistent sadness and suicidal thoughts, MDD is the fourth leading cause of death among individuals aged 15–29 years, accounting for more than 700,000 suicides annually. MDD is more common in women and is considered a multifactorial disorder resulting from the combined influence of genetic, epigenetic, psychological, biological, and environmental factors. Despite advances in treatment, currently available interventions, including antidepressant medications and psychotherapy, have important limitations, and relapse remains common. Furthermore, there is currently no reliable biomarker available to predict treatment response.

The purpose of this study is to identify potential biomarkers that may assist healthcare professionals in clinical decision-making and predict treatment response by evaluating the clinical, neurophysiological, and inflammatory characteristics of individuals experiencing a major depressive episode who have been referred for electroconvulsive therapy (ECT).

A total of **31 patients** aged between **18 and 60 years** who have been diagnosed with Major Depressive Disorder and are experiencing a major depressive episode, together with **31 healthy volunteers**, will be enrolled in this study on a voluntary basis.

For participants in the patient group, a clinical assessment, collection of a blood sample, and a **10-minute EEG recording** will be performed before the first ECT session. Two weeks after completion of the ECT treatment course, participants will undergo a second clinical assessment, blood sampling, and EEG recording. Eight weeks after completion of ECT, a final clinical assessment, blood sample, and 10-minute EEG recording will be obtained.

Healthy volunteers will participate in a single study visit consisting of one clinical assessment, one blood sample collection, and one 10-minute EEG recording.

Approximately one-third of patients with Major Depressive Disorder do not achieve complete remission despite receiving two adequate trials of antidepressant treatment. Identification of clinically useful biomarkers may contribute to improved treatment outcomes for future patients.

Your participation in this study will contribute to the advancement of scientific knowledge and may help improve future treatment approaches for Major Depressive Disorder. No foreseeable risks related to participation are anticipated beyond those associated with standard clinical procedures. You will not be charged any fee for participating in this study, nor will you receive any financial compensation for your participation.

All personal information collected during this study will be kept strictly confidential and will not be disclosed publicly. Medical information obtained during the study will be used solely for research purposes. However, if required, study records may be reviewed by authorized monitors, ethics committees, or regulatory authorities for quality assurance and regulatory compliance.

Participation in this study is entirely voluntary. You may refuse to participate or withdraw your consent at any time without providing a reason. Refusal to participate or withdrawal from the study will not affect the medical care or treatment you receive.

Research Team

- Dr. Zeynep Ozge Dagoglu Sarac, MD
- Dr. Yusuf Cicek, MD
- Dr. Ahmet Torun, MD
- Associate Professor Alperen Kilic, MD
- Professor Burc Cagri Poyraz, MD

Participant's Statement

The nature and purpose of this research study have been explained to me by the investigators, and I have been provided with the information presented above. I have been invited to participate in this study as a research participant. If I choose to participate, I understand that my personal and medical information will be treated with the utmost confidentiality throughout the study. I have been assured that my identity will be protected during the scientific analysis, publication, and presentation of the study findings.

I understand that I may withdraw from the study at any time without providing any reason.

If I experience any health-related problems during the study or require additional information, I understand that I may contact **Dr. Zeynep Ozge Dagoglu Sarac, MD** at **+90 536 594 24 69** or at the **Department of Psychiatry, Cerrahpaşa Faculty of Medicine, Istanbul University-Cerrahpaşa**.

I confirm that all aspects of this study have been explained to me in sufficient detail by the investigators, that I have understood the information provided, and that I voluntarily agree to participate in this study as a participant.

Participant's Name: _____

Signature: _____

Date / Time: _____

Witness's Name: _____

Signature: _____

Date / Time: _____

First-Degree Relative (if applicable): _____

Signature: _____

Date / Time: _____

Investigator's Name: _____

Signature: _____

Date / Time: _____