CLINICALTRIALS.GOV DOCUMENT COVER PAGE

Official Title

The Relationship Between EEG Microstate Parameters, Neuroinflammatory Biomarkers and Treatment Response in Older Patients With Major Depressive Disorder or Bipolar Disorder Undergoing Electroconvulsive Therapy During a Major Depressive Episode

ClinicalTrials.gov Identifier (NCT Number)	Pending
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Sponsor	Istanbul University-Cerrahpasa, Cerrahpasa Faculty of Medicine
Principal Investigator	Zeynep Ozge Dagoglu Sarac, MD
Study Site	Department of Psychiatry, Cerrahpasa Faculty of Medicine, Istanbul University-C
Estimated Study Start Date	December 1, 2025
Estimated Primary Completion Date	December 2026
Estimated Study Completion Date	February 2027

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 Between Microstructural Parameters, Neuroinflammatory Biomarkers, and Treatment Response in Older Patients With Major Depressive Disorder or Bipolar Disorder Undergoing Electroconvulsive Therapy During a Major Depressive Episode

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 support clinical decision-making and predict treatment response by evaluating the clinical, neurophysiological, and inflammatory characteristics of older adults experiencing a major depressive episode who have been referred for electroconvulsive therapy (ECT).

A total of **31 patients aged 55 years or older** diagnosed with Major Depressive Disorder and experiencing a major depressive episode, together with **31 healthy volunteers**, will be enrolled on a voluntary basis.

For participants in the patient group, a clinical assessment, blood sample collection, 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 sample collection, and EEG recording. Eight weeks after completion of ECT, a final clinical assessment, blood sample collection, and a 10-minute EEG recording will be performed.

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 fail to 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 strategies for depression. No foreseeable risks beyond those

associated with routine clinical procedures are anticipated. 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 from the study at any time without providing a reason. Your decision to withdraw or not to participate will not affect your medical care or treatment in any way.

Research Team

- Dr. Zeynep Ozge Dagoglu Sarac, MD
- Associate Professor Alperen Kilic, MD

Participant's Statement

The investigators have explained the nature and purpose of this medical research to me, 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 all personal and medical information concerning me will remain confidential and will be handled with the utmost respect 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** at **+90 536 594 2469** 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.

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: _____