

# Pivotal-Safety and Therapeutic Measures of tDCS in Patients With Refractory Focal Epilepsy

NCT04770337

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Neuroelectrics Corporation
Enrollment	190 participants

## Key Eligibility Criteria

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### Inclusion (12)

- years old or older
- Diagnosis of epilepsy with focal seizures with or without focal to bilateral tonic clonic seizures (International League Against Epilepsy classification). Diagnosis established by both clinical history and an EEG consistent with focal seizures.
- Note: A normal interictal EEG is consistent with focal seizures, if other data is adequate to provide localization.
- Epilepsy is refractory to treatment, defined as: failure to achieve adequate seizure control despite demonstrated compliance, according to medical records, on at least two (2) FDA-approved ASDs at a daily dose considered therapeutic for the patient's demographic according to package labeling, within approximately the last 3 years.
- Seizure frequency  $\geq 3$  per month, over the past year.

... and 7 more (see full listing online)

### Exclusion (15)

- Presence of a condition or abnormality that in the opinion of the Investigator would compromise the safety of the subject or the integrity of the data.
- Evidence for more than one seizure focus. (NOTE: For this study, a seizure focus is defined as a cortical region confined to one hemisphere and either one lobe or on a junction of two adjacent lobes from which seizures arise, as documented by scalp or intracranial EEG, that is either supported or not refuted by MRI, and either supported or not refuted by clinical semiology). If the interictal EEG is normal, a seizure focus may be identified by the combination of structural findings on MRI and clinical signs/symptoms associated with the subject's seizures.
- Seizure focus is one of: interhemispheric, cingulate, or orbitofrontal
- Seizure focus is hemispheric or poorly defined
- History of psychogenic nonepileptic seizures in past 2 years, or physiologic nonepileptic seizures and non-epileptogenic events, including suspicion for or a significant history of syncope, and any non-epileptic events must be clearly differentiable from subject's focal seizures based on previously recorded video EEG showing distinct clinical and electrographic features of the subject's PNES compared to their epileptic seizures.

... and 10 more (see full listing online)

## Locations (32 total)

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Barrow Neurological Institute, St. Joseph's Hospital & Medical Center, Phoenix, Arizona, United States

Loma Linda University Health, Loma Linda, California, United States

Keck Medicine of USC, Los Angeles, California, United States

... and 29 more locations

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<https://clinicaltrials.gov/study/NCT04770337>

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