

Double-blind, Randomized Clinical Trial Evaluating the Efficacy and Safety of Vormatrigine in Adults With Focal Seizures

NCT07505004

Status	RECRUITING
Phase	Phase 3
Sponsor	Praxis Precision Medicines
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (5)

- Has a diagnosis of focal onset epilepsy according to the International League Against Epilepsy Classification of Epilepsy (2017).
- Prior to randomization, past evidence by CT or MRI that has ruled out a progressive cause of epilepsy in the judgement of the investigator and/or in consultation with the medical monitor.
- Participant must attest to be taking stable doses of 1 or up to 3 acceptable ASMs for at least 4 weeks prior to screening and during screening prior to Day 1.
- Has at least 4 countable focal onset seizures during the 4 weeks of Observation Period immediately prior to randomization with no more than 21 days seizure free during this period.
- Seizure diary must be completed for e80% days in the Observation Period.

Exclusion (25)

- Participant has had any of the following within the 12-month period preceding trial entry:
 - evidence of experiencing pseudo or psychogenic seizures
 - cluster seizures where the individual seizures cannot be counted
 - an episode of convulsive status epilepticus requiring hospitalization and intubation
 - seizures secondary to illicit drug or alcohol use
- ... and 20 more (see full listing online)

Locations (7 total)

Praxis Research Site, Miami, Florida, United States
Praxis Research Site, Miami Lakes, Florida, United States
Praxis Research Site, Naples, Florida, United States
... and 4 more locations

<https://clinicaltrials.gov/study/NCT07505004>

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