

Study to Determine if BHV-7000 is Effective and Safe in Adults With Refractory Focal Onset Epilepsy

NCT06309966

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Biohaven Therapeutics Ltd.
Enrollment	390 participants

Key Eligibility Criteria

Inclusion (6)

- Male and Female participants 18 to 75 years of age at time of consent.
 - Diagnosis of Focal Onset Epilepsy at least 1 year prior to screening visit defined by 2017 International League Against Epilepsy (ILAE) Classification and based on requirements of Epilepsy Adjudication criteria.
 - a. Focal seizures i. Focal aware seizures with clinically observable signs and/or symptoms ii. Focal impaired awareness seizures with clinically observable signs and/or symptoms iii. Focal to bilateral tonic-clonic seizures
 - Subject meets the 2009 ILAE definition of drug resistant epilepsy, failure of adequate trials of two tolerated and appropriately chosen and used anti-seizure medication (ASM) schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom.
 - Ability to keep accurate seizure diaries
- ... and 1 more (see full listing online)

Exclusion (6)

- History of status epilepticus (convulsive status epilepticus for \gt 5 minutes or focal status epilepticus with impaired consciousness for \gt 10 minutes) within the last 6 months prior to screening visit that is not consistent with the subject's habitual seizure.
 - History of repetitive/cluster seizures (where individual seizures cannot be counted) within the last 6 months prior to screening visit and during observation phase.
 - Resection neurosurgery for seizures \lt 4 months prior to the screening visit.
 - Radiosurgery performed \lt 2 years prior to the screening visit.
 - Subjects with only focal aware nonmotor seizures which involve subjective sensory or psychic phenomena only, without impairment of consciousness or awareness (formally called simple partial seizures), with or without ictal EEG correlation with clinical symptoms.
- ... and 1 more (see full listing online)

Locations (172 total)

Accel Research, Birmingham, Alabama, United States
Onyx Clinical Trials, Peoria, Arizona, United States
Xenoscience, Inc., Phoenix, Arizona, United States
... and 169 more locations