A Study to Evaluate Efficacy and Safety of Perampanel Administered as an Adjunctive Therapy in Pediatric Participants With Childhood Epilepsy

NCT04015141

Status	RECRUITING
Phase	Phase 2
Sponsor	Eisai Inc.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (5)

- Male or female participants. Cohort 1: age 1 month to less than 18 years; Cohort 2: age 1 month to less than 2 years at the time of informed consent/assent. Participants below the age of 1 year must have been at least 36 weeks of gestational age at birth.
- Have a diagnosis of epilepsy with a pediatric epileptic syndrome (Cohort 1) or epilepsy with POS with or without secondary generalization (Cohort 2).
- Have had equal or greater than 4 seizures over the 4-week interval prior to enrollment visit.
- Absence of any progressive cause of epilepsy that has been confirmed clinically or based on brain imaging (example, magnetic resonance imaging \[MRI\] scan or computed tomography \[CT\] or ultrasound \[for less than 1 year old\]).
- Currently maintained on stable doses of 1 to a maximum of 4 approved antiepileptic drugs (AEDs). A prescription medical marijuana (including products containing cannabidiol) is counted as 1 of the maximum of 4 allowed AEDs; however, it cannot be the only concomitant AED if this product is not an approved AED in the country where the study site is located. Doses must be stable for at least 4 weeks (at least 2 weeks for participant less than \[\<\] 6 months old) before Visit 1/Baseline or screening; only 1 enzyme-inducing antiepileptic drug (EIAED) (defined as carbamazepine, phenytoin, oxcarbazepine, or eslicarbazepine) out of the maximum of 4 AEDs is allowed.

Exclusion (10)

- Current or history of pseudo-seizures (psychogenic nonepileptic seizures) within approximately 5 years before screening visit.
- Have a history of status epilepticus that required hospitalization within 6 months before screening visit.
- Have an unstable psychiatric diagnosis that may confound participant's ability to participate in the study or that may prevent completion of the protocol specified tests (example, significant suicide risk, including suicidal behavior and ideation within 6 months before screening visit 1, current psychotic disorder, acute mania).
- Any suicidal ideation with intent with or without a plan within 6 months before enrollment visit (answering "Yes" to questions 4 or 5 on the Suicidal Ideation section of the C-SSRS) in participants aged 6 and above or based on the opinion of the Investigator for participants less than 6 years.
- Are scheduled or confirmed or both to have epilepsy surgery within 6 months after screening visit; however, those who have previously documented "failed" epilepsy surgery will be allowed.

... and 5 more (see full listing online)

Locations (49 total)

Phoenix Childrens Hospital, Phoenix, Arizona, United States
Center For Neurosciences, Tucson, Arizona, United States
David Geffen School of Medicine at UCLA, Los Angeles, California, United States
... and 46 more locations