A Clinical Trial for Participants With DEE to Assess Efficacy, Safety, Tolerability, and PK of Relutrigine

NCT07010471

Status	RECRUITING
Phase	Phase 3
Sponsor	Praxis Precision Medicines
Enrollment	160 participants

Key Eligibility Criteria

Inclusion (3)

- Has a documented diagnosis of a developmental and epileptic encephalopathy.
- Onset of seizures \<12 years old.
- Has a weight \>7 kg at the time of signing consent/assent.

Exclusion (6)

- Has a history of left bundle branch block, arrhythmias, Brugada syndrome, congenital heart disease, familial short QT syndrome, or family history of sudden death or ventricular arrhythmias, including idiopathic ventricular fibrillation.
- Had 2 or more episodes of convulsive status epilepticus requiring hospitalization and intubation in the 6 months prior to Screening.
- Has an abnormal ECG reading, including a QT interval corrected for heart rate using Bazett's method (QTcB) \<350 and \>450 ms (males), or \<360 and \>460 ms (females) at Screening and/or on Day 1.
- Any nerve stimulation must have been placed at least 3 months prior to Screening with at least 1 month of stable settings prior to Screening.
- Has received any other experimental or investigational drug, device, or other therapy within 30 days or 5 half-lives (whichever is longer) prior to Screening, including any prior use of gene therapy.

... and 1 more (see full listing online)

Locations (5 total)

Praxis Research Site, La Jolla, California, United States
Praxis Research Site, Gulf Breeze, Florida, United States
Praxis Research Site, Chevy Chase, Maryland, United States
... and 2 more locations