

A Double-blind Study Evaluating the Efficacy, Safety, and Tolerability of Zorevunersen in Patients With Dravet Syndrome

NCT06872125

Status	RECRUITING
Phase	Phase 3
Sponsor	Stoke Therapeutics, Inc
Enrollment	170 participants

Key Eligibility Criteria

Inclusion (8)

- Patients must be ≥2 and <18 years of age.
- Patients must have a clinical diagnosis of DS confirmed by the Epilepsy Study Consortium, Inc. (ESCI) and as defined by:
- Onset, prior to 12 months (inclusive, <13 months), of age, of recurrent focal with motor signs, hemiclonic, or generalized tonic-clonic seizures. No other known etiology causing clinical DS manifestations..
- Patient must have a documented pathogenic, likely pathogenic variant, or variant of uncertain significance in the sodium voltage-gated channel type 1 alpha subunit (SCN1A) gene. Patients who have SCN1A testing results of Negative (no variants identified) cannot be randomized.
- Patient must experience the required number of major motor seizures during the 6-week Observation Period. Major motor seizure types included are Seizure types included in counts are Hemiclonic, Focal with Motor Signs, Focal to Bilateral Tonic-Clonic, Generalized Tonic-Clonic, Tonic, Tonic/Atonic (Drop Attacks with fall or risk of fall), and Bilateral Clonic.

... and 3 more (see full listing online)

Exclusion (4)

- Patient has documented variant in the SCN1A gene associated with gain-of-function
- Patient is currently treated with a maintenance ASM acting primarily as a sodium channel blocker, including but not limited to phenytoin, carbamazepine, oxcarbazepine, lamotrigine, lacosamide, rufinamide, or cenobamate, given the mechanism of action of zorevunersen.
- Patient is currently treated with neuromodulation techniques (e.g., responsive neurostimulation, deep brain stimulation, or transcranial magnetic stimulation), with the exception of VNS.
- Patient has emergence of a new seizure type or reemergence of a past seizure type (seizure types that last occurred more than 12 months before Screening Visit A) during the Baseline Period, or has more than 1 hospitalization for seizures during the Baseline Period.

Locations (45 total)

Phoenix Children's Hospital, Phoenix, Arizona, United States
Arkansas Children's Hospital, Little Rock, Arkansas, United States
Cedars Sinai Medical Center, Los Angeles, California, United States
... and 42 more locations

<https://clinicaltrials.gov/study/NCT06872125>

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