A Study of EPX-100 (Clemizole Hydrochloride) in Participants With Dravet Syndrome

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 2 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Key Inclusion Criteria:

1. Male and female participants 2 years and older at time of consent.
2. Participant or parent/legally authorized representative (LAR) willing and able to provide written informed consent and assent (if applicable) prior to initiation of any study related procedures.
3. Clinical diagnosis of DS. Participants must have seizures which are not completely controlled by AEDs with the following criteria:

- Onset of seizures prior to 18 months of age,
- Normal development at onset,
- History of at least one type of countable motor seizure (CMS),
- Brain MRI without cortical malformation (not including mild atrophy associated with the natural progression of DS),
- Genetic mutation of the SCN1A gene must be documented.

Key Exclusion Criteria:

1. Known sensitivity, allergy, or previous exposure to clemizole HCl.
2. Exposure to any investigational drug or device <90 days prior to screening or plans to participate in another drug or device trial at any time during the study.
3. Seizures secondary to illicit drug (this includes concomitant use of tetrahydrocannabinol [THC] and nonprescription cannabidiol preparations) or alcohol use, infection, neoplasm, demyelinating disease, degenerative neurological disease, or central nervous system disease deemed progressive, metabolic illness, or progressive degenerative disease.
4. Concurrent use of lorcaserin. Note: Prior use of lorcaserin is permitted if at least 30 days have passed since the last dose.
5. Concurrent use of fenfluramine.
6. Epilepsy surgery planned during the study or epilepsy surgery within 6 months prior to Screening.

Conditions & Interventions

Interventions:
DRUG: Clemizole HCl, DRUG: Placebo
Conditions:
Dravet Syndrome
Keywords:
Clemizole hydrochloride, Convulsive seizure, Pediatric epilepsy, Dravet syndrome

More Information

Description:
This is a multicenter, Phase 3, randomized, double-blind, placebo-controlled study designed to evaluate the efficacy and safety of clemizole hydrochloride (EPX-100) as adjunctive therapy in children and adult participants with Dravet syndrome (DS).

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