

# A First-in-human Study of S230815 in Pediatric Participants With KCNT1-related Developmental and Epileptic Encephalopathy

NCT07227857

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 1, Phase 2
<b>Sponsor</b>	Institut de Recherches Internationales Servier
<b>Enrollment</b>	20 participants

## Key Eligibility Criteria

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### Inclusion (2)

- Male or female pediatric participants aged 2-12 years old at screening, with a genetically confirmed diagnosis of Developmental Epileptic Encephalopathy (DEE) due to a pathogenic or likely pathogenic variant in KCNT1 confirmed by central genetic testing.
- Stable dose of other regular medications and/or stable antiseizure interventions (such as ketogenic diet and vagal nerve stimulation).

### Exclusion (19)

- Other clinical phenotypes associated with pathogenic or likely pathogenic variants in KCNT1 other than Epilepsy of Infancy with Migrating Focal Seizures or Early-Onset Epileptic Encephalopathy
- Documented pathogenic or likely pathogenic variants in any other gene known to cause epilepsy identified through prior genetic testing. Variants of uncertain significance in other genes known to cause epilepsy may be considered on discussion with the sponsor.
- Clinically significant medical history or clinical findings on physical examination, other than DEE, that in the judgment of the investigator, make the participant unsuitable for participation in the study and/or completion of the trial procedures, including, but not limited to:
- Clinically significant prior or ongoing medical conditions within 30 days of the screening visit, as per investigator judgement.
- Clinically significant abnormality on Electrocardiogram (ECG) at the screening visit, as per investigator judgement.

... and 14 more (see full listing online)

## Locations (16 total)

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Children's Hospital of Orange County, Orange, California, United States  
Boston Children's Hospital, Boston, Massachusetts, United States  
University of Rochester Medical Center, Rochester, New York, United States  
... and 13 more locations