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Refractory Status Epilepticus
Phase 3 Clinical Trial
Amendment 3/10Jun2022

SCAN FOR INFO

Inclusion Criteria:

1. **Consent:** Participant, participant's parent, guardian, or LAR must provide signed informed consent/assent, and once capable (per institution guidelines), there must be documentation of consent/assent by the participant demonstrating they are willing and aware of the investigational nature of the study and related procedures.
2. **Age:** Male or females 18 years of age and older at the time of the first dose of IP
3. **SE: A diagnosis of SE with or without prominent motor features based on clinical and EEG findings:**
   - **For SE with prominent motor features: Clinical and EEG seizure activity indicative of convulsive, myoclonic or focal motor SE**
   - **For SE without prominent motor features (nonconvulsive SE): Appropriate clinical features and an EEG indicative of NCSE**
   - **For any type of SE:**
     At least 6 minutes of cumulative seizure activity over a 30-minute period within the hour before IP initiation, AND
     Seizure activity during the 30 minutes immediately prior to IP initiation

   The treating clinician(s) anticipate that IV anesthesia is likely to be the next treatment for SE that persists following initiation of IP
4. **Failed 2 or more antiseizure treatments:** Participants **must have received** <u>any two or more</u> of the following agents for treatment of the current episode of SE administered at an adequate dose and for a sufficient duration, in the judgment of the investigator, to demonstrate efficacy: **benzodiazepines, IV fosphenytoin/ phenytoin, IV valproic acid, IV levetiracetam, IV lacosamide, IV brivaracetam, or IV phenobarbital**
5. **BMI < 40** or, if BMI is not able to be calculated at screening, participant is assessed by investigator as not morbidly obese

24-hour Study Team Contact:

(PI)

(SC)

Exclusion Criteria:

1. **Life expectancy** of less than 24 hours
2. **Anoxic brain injury** or an uncorrected rapidly reversable metabolic condition as the primary cause of SE (e.g., hypoglycemia <50mg/dL or hyperglycemia >400mg/dL)
3. **SRSE:** Participants who have received high-dose IV anesthetics (e.g., midazolam, propofol, thiopental, or pentobarbital) during the current episode of SE for more than 18 hours, or who continue to have clinical or electrographic evidence of persistent seizures while receiving high-dose IV anesthetics.
4. **Not a candidate for IV anesthesia:** Clinical condition or advance directive that would NOT permit use of IV anesthesia
5. Participants known or suspected to be **pregnant**
6. Participants with known **allergy or sensitivity** to progesterone or allopregnanolone medications/ supplements
7. Receiving a concomitant IV product containing **Captisol®**
8. Known or suspected **hepatic insufficiency** or hepatic failure leading to impaired synthetic liver function.
9. Known or suspected stage 3B (moderate to severe; eGFR 44-30 mL/min/1.73m^2), stage 4 (severe; eGFR 29-15 mL/min/1.73m^2), or stage 5 (**kidney failure**; eGFR < 15 mL/min/1.73m^2 or dialysis) kidney disease
10. **Use of an IP** for which less than 30 days or 5 half-lives have elapsed from the final product administration. Participation in a non-interventional clinical study does not exclude eligibility.