Purpose

The purpose of this study is to evaluate the safety and tolerability of SAGE-547 in subjects in s

Condition	Intervention
Super-refractory Status Epilepticus	Drug: SAGE-5

Study Type: Interventional
Study Design: Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: An Open-label Study to Evaluate the Safety, Efficacy, and Pharmacokinetics of Treatment of Super-Refractory Status Epilepticus

Resource links provided by NLM:

Genetic and Rare Diseases Information Center resources: Status Epilepticus

U.S. FDA Resources

Further study details as provided by Sage Therapeutics:

Primary Outcome Measures:

- Safety and tolerability in subjects in super-refractory status epilepticus (SRSE) [Time Fram

  Safety will be evaluated via clinical laboratory measures, vitals, EEG and ECG throughout t

Secondary Outcome Measures:

- Efficacy of SAGE-547 on super-refractory status epilepticus as indicated by the need to re- refractory seizure control as well as the duration of the observed response [Time Frame: 9
- Pharmacokinetics (PK) of SAGE-547 exposure [Time Frame: 7 Days] [Designated as saf

  Plasma PK parameters will be calculated where appropriate (eg, Cmax, Cmin, Tmax, AUC

ongoing treatment for all underlying medical conditions.

Eligibility

Ages Eligible for Study:	2 Years and older (Child, Adult, Senior)
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Subjects 2 years of age and older.
- Subjects with an EEG-confirmed SRSE diagnosis under concomitant therapy with a continu study, SRSE is defined by the following criteria and in accordance with those used at major
  - Failure to respond to the administration of at least one first-line agent (e.g., benzodiaze according to institution standard of care, and
  - Failure to respond to at least one second-line agent (e.g., phenytoin, fosphenytoin, valp control AED) according to institution standard of care, and
  - Presence of one or more breakthrough seizures > 6 hours after initiation of the continuo midazolam, propofol)

Exclusion Criteria:

- Subjects with SRSE due to anoxic/hypoxic encephalopathy, children (subjects aged less th underlying progressive neurological disorder.
- Subjects with clinically significant electrocardiogram (ECG) abnormalities.
- Subjects with a significant medical or surgical condition that may compromise vital organ sy subject at increased risk such as dialysis or acute respiratory distress syndrome, severe ca pressors, fulminant hepatic failure, etc.
- Subjects who are receiving a continuous IV AED (third-line agent) for seizure suppression hours to wean.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and f study. To learn more about this study, you or your doctor may contact the study research staff u information, see Learn About Clinical Studies.

New Orleans, Louisiana, United States, 70121

United States, Massachusetts

Massachusetts General Hospital
Boston, Massachusetts, United States, 02114

Brigham and Women's Hospital
Boston, Massachusetts, United States, 02115

United States, Michigan

University of Michigan
Ann Arbor, Michigan, United States, 48109

Henry Ford Hospital
Detroit, Michigan, United States, 48322

United States, New York

Columbia University Medical Center
New York, New York, United States, 10032

University of Rochester
Rochester, New York, United States, 14642

United States, North Carolina

Duke University Medical Center
Durham, North Carolina, United States, 27710

Wake Forest
Winston-Salem, North Carolina, United States, 27157

United States, Pennsylvania

The University of Pennsylvania
Philadelphia, Pennsylvania, United States, 19104

United States, Tennessee

Vanderbilt University Medical Center
Nashville, Tennessee, United States, 37232

United States, Texas

Neurological Clinic of Texas, PA
Dallas, Texas, United States, 75251

Super-refractory status epilepticus	Sage Therapeutics

Additional relevant MeSH terms:
Status Epilepticus
Epilepsy
Brain Diseases
Central Nervous System Diseases
Nervous System Diseases

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