

A Phase 1/2 Study of NRTX-1001 Neuronal Cell Therapy in Drug-Resistant Bilateral Mesial Temporal Lobe Epilepsy (MTLE)

NCT06422923

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Neurona Therapeutics
Enrollment	10 participants

Key Eligibility Criteria

Inclusion (12)

- Male or female, age 18-75 years.
 - Subjects of childbearing potential will use highly effective contraception.
 - Proven history of focal seizures of hippocampal origin with bilateral seizure foci confirmed by scalp or intracranial ictal EEG (including confirmation by recordings from responsive neurostimulation [RNS] electrodes when applicable).
 - Either
 - bilateral hippocampal sclerosis on MRI (evidenced by increased FLAIR signal intensity in both hippocampi or by visual assessment showing reduced volume compared to normal) or
- ... and 7 more (see full listing online)

Exclusion (11)

- Epilepsy due to other and/or progressive neurologic disease.
 - Evidence of seizure focus outside hippocampus (either by seizure semiology or EEG findings).
 - MRI indicating potential malignant lesion (low-grade glioma of any type is excluded) in any location or non-malignant potentially epileptogenic lesion outside the hippocampus. Small (<2 cm) non invasive meningioma, remote from the affected temporal lobe, is not exclusionary.
 - Seizures of non-focal origin.
 - History of status epilepticus in the year prior to screening, as guided by ILAE criteria (Trinka 2015) in the judgement of the PI. A history of cluster seizures is permitted.
- ... and 6 more (see full listing online)

Locations (17 total)

University of Arkansas for Medical Sciences, Little Rock, Arkansas, United States
University of Southern California Keck Hospital, Los Angeles, California, United States
UC Irvine Medical Center, Orange, California, United States
... and 14 more locations

<https://clinicaltrials.gov/study/NCT06422923>

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