

Evaluation of the NaviFUS System in Drug Resistant Epilepsy

NCT05947656

Status	RECRUITING
Phase	Not Applicable
Sponsor	Genovate-NaviFUS (Australia) Pty Ltd.
Enrollment	18 participants

Key Eligibility Criteria

Inclusion (7)

- Diagnosis of drug resistant temporal lobe epilepsy (TLE)
- Patients must experience at least four (4) observable seizures over the 60-day baseline, each on a separate day.
- Patients have focal-onset seizures with or without secondary generalization.
- Patients have had at least 24 hours video-electroencephalography (EEG) monitoring and comprehensive epilepsy evaluation confirming TLE.
- Seizure medication treatment is anticipated to remain stable during the trial, except for rescue medicines or occasional extra doses of ongoing medicines, as required.

... and 2 more (see full listing online)

Exclusion (17)

- Patients who have primary generalized epilepsy or non-epileptic seizures in the last two (2) years.
- More than two (2) seizure onset zones (foci) (except bitemporal foci) or unknown likely site of seizure onset, as determined by usual clinical, electroencephalography (EEG) and imaging practice.
- Patients who have experienced tonic-clonic status epilepticus in the three (3) months leading up to enrollment in the study.
- Presence of devices including but not limited to cardiac pacemaker, implantable cardioverter-defibrillator (ICD), permanent medication pumps, cochlear implants, responsive neurostimulator (RNS) or deep brain stimulation (DBS). Vagus nerve stimulators (VNS) do not represent an exclusion criterion, but settings should be stable throughout the trial.
- Patients with clips or other metallic implanted objects in the FUS exposure path, except shunts.

... and 12 more (see full listing online)

Locations (1 total)

The Alfred, Melbourne, Victoria, Australia

<https://clinicaltrials.gov/study/NCT05947656>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).