A Pilot Study to Evaluate the Efficacy and Safety of NaviFUS™ System Neuromodulating Treatment for Patients With Drug Resistant Epilepsy

NCT06492720

Status	RECRUITING
Phase	Not Applicable
Sponsor	NaviFUS Corporation
Enrollment	16 participants

Key Eligibility Criteria

Inclusion (5)

- Male or female patients aged over than and equal to 18 years old.
- Patients with drug-resistant epilepsy (defined as at least 3 ASM failed) and 1-4 ASM at the time of study entry.
- Epileptogenic focus (or foci) is determined by comprehensive presurgical evaluation.
- At least 4 focal-onset seizures with objectively visible or significantly disabling manifestations in the 8-week baseline and at least one seizure per month in the baseline.
- Willing and able to sign written informed consent and be able to comply with the study protocol during the study period.

Exclusion (21)

- Patients with concurrent active psychiatric or mood disorders that have been assessed to interfere with participation in the study.
- Presence of pacemaker, implantable cardioverter-defibrillator (ICD), permanent medication pumps, cochlear implants, or deep brain stimulation (DBS).
- The skull bone area traversed by the sonication pathway is covered by scars, scalp disorders (e.g., eczema), wounds, or atrophy of the scalp.
- Image documented calcified lesion in the FUS exposure path.
- Abnormal coagulation profile:

... and 16 more (see full listing online)

Locations (1 total)

Taipei Veterans General Hospital, Taipei, Taiwan