

ONO-2017 Study Japanese Patients With Primary Generalized Tonic Clonic Seizures.

NCT06579573

Status	RECRUITING
Phase	Phase 3
Sponsor	Ono Pharmaceutical Co. Ltd
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (4)

- Gender and age: Japanese patients, regardless of gender, aged 12 years or older at the time of informed consent.
- Subject has a clinical diagnosis of Primary Generalized Tonic-Clonic (PGTC) seizures in the setting of idiopathic generalized epilepsy.
- Subject experiences at least 5 Primary Generalized Tonic-Clonic (PGTC) seizures in 12 weeks.
- Subject is currently receiving 1 to a maximum of 3 concomitant Antiepileptic Drugs(AEDs) with fixed dosing regimens

Exclusion (5)

- Subject has a history of status epilepticus that required hospitalization within 15 months prior to enrollment.
- Subject has seizure clusters where individual seizures cannot be counted or classified.
- History of non-epileptic or psychogenic seizures.
- Subject has a concomitant diagnosis of Partial Onset Seizure(POS).
- Subject has a history of any serious drug-induced hypersensitivity reaction (including but not limited to Stevens Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms(DRESS), Drug-induced hypersensitivity syndrome(DIHS)) or any drug-related rash requiring hospitalization.

Locations (25 total)

Aichi Medical University Hospital, Aichi, Japan
Hospital of the University of Occupational and Environmental Health, Japan, Fukuoka, Japan
Southern TOHOKU Research Institute for Neuroscience Southern TOHOKU Medical Clinic, Fukushima, Japan
... and 22 more locations