Real-world Clinical Response to Cenobamate Early add-on in France, Germany and Spain

NCT06716801

Status	RECRUITING
Sponsor	Aziende Chimiche Riunite Angelini Francesco S.p.A
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (6)

- Male and female patients e18 years old at the time of cenobamate treatment initiation.
- Patients with a diagnosis of epilepsy with focal-onset seizures, with or without secondary generalization.
- Patients under titration phase (i.e., maintenance dose not reached yet according to clinical judgement) with cenobamate as adjunctive therapy in third or fourth line with 1 to maximum 2 (for third line)/3 (for fourth line) concomitant anti-seizure medications (ASMs).
- Patients who have not been adequately controlled despite treatment with 2 or 3 (maximum) ASMs before cenobamate treatment initiation (including concomitant ASMs started before initiating cenobamate).
- Patients with available retrospective data in medical charts, seizure diaries or patient's notes, including reliable information about seizure frequency (intended as the number of seizures and the corresponding time period) in the last 3 months before cenobamate treatment initiation.

... and 1 more (see full listing online)

Exclusion (7)

- Patients who meet any of the contraindications to the administration of cenobamate according to its approved Summary of Product Characteristics (SmPC).
- Patients with progressive neurodegenerative central nervous system (CNS) diseases or (benign or malignant) brain tumors.
- Patients with unstable psychiatric diagnosis, including suicidal ideation and behavior within 6 months prior to enrolment, current psychotic disorder, or acute mania.
- Patients with known substance abuse or dependence (except for caffeine and nicotine).
- Patients participating in any interventional study from cenobamate treatment initiation until enrolment visit.

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

Locations (1 total)

Hôpital TARNIER COCHIN, Paris, France, France