A Prospective, Non-Interventional, Observational, Multicenter Study to Investigate Dosage, Effectiveness, and Safety of Perampanel When Used as First Adjunctive Therapy in the Routine Clinical Care of Subjects >=12 Years With Partial Onset Seizures With or Without Secondary Generalization or With Primary Generalized Tonic-Clonic Seizures Associated With Idiopathic Generalized Epilepsy

First published: 13/07/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS105866

Study ID

105877

DARWIN EU® study

No

Study countries

- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Portugal
- [ ] Russian Federation
- [ ] Spain

Study description

The main aim of the study was to assess the retention rate of perampanel as a reliable proxy for overall effectiveness and tolerability in participants aged at least 12 years who were prescribed perampanel (for partial onset seizures POS with or without secondary generalization SG or for primary generalized tonic-clonic seizures PGTCS associated with idiopathic generalized epilepsy IGE) as first adjunctive to antiepileptic drug (AED) monotherapy as part of their routine clinical care.

Study status

Finalised

Research institutions and networks

Institutions

Eisai

First published: 01/02/2024

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Institution

Multiple centres: 38 centres are involved in the study

Contact details

Study institution contact

Eisai Medical Information Clinicaldisclosure@eisai.net

Study contact

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Primary lead investigator

Eisai Medical Information

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/03/2020

Study start date
Actual: 20/07/2020

Data analysis start date
Actual: 12/01/2023

Date of final study report
Planned: 30/06/2023

Actual: 04/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai Ltd.

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Other study registration identification numbers and links

ClinicalTrials.gov Identifier: NCT04252846

Methodological aspects

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Investigate Dosage

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study was to assess the retention rate of perampanel as a reliable proxy for overall effectiveness and tolerability in participants aged at least 12 years who are prescribed perampanel (for POS with or without SG or for PGTCS associated with IGE) as first adjunctive to AED monotherapy as part of their routine clinical care.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational, prospective, multicenter study

Study drug and medical condition

Name of medicine

FYCOMPA

Medical condition to be studied

Idiopathic generalised epilepsy

Generalised tonic-clonic seizure

Additional medical condition(s)

Partial Onset Seizures

Population studied

Short description of the study population

The study population included subjects aged ≥12 to 65 years diagnosed with epilepsy (partial onset seizures with or without secondary generalization or with primary generalized tonic–clonic seizures associated with idiopathic generalized epilepsy) who had prescribed treatment with perampanel as first adjunctive to antiepileptic drug (AED) monotherapy as part of their routine clinical care.
Inclusion criteria:
Subjects were eligible for participation in the study if they were at least 12 years of age at screening and had a diagnosis of epilepsy and a history of POS with or without SG or PGTCS associated with IGE (according to the International League Against Epilepsy [ILAE] Classification of Epileptic Seizures, 1981 and ILAE Classification of Epileptic Syndromes, 1989) who had previously been

treated with 1 or 2 AEDs as monotherapy.

Exclusion criteria:
Subjects with previous or current use of perampanel at the time of screening were excluded.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Special population of interest

Other

Special population of interest, other

Patients with epilepsy

Estimated number of subjects

300

Study design details

Outcomes

The primary outcome assessed the percentage of participants remaining on perampanel (retention rate) at 12 months. Assess perampanel retention rate at 6 months, pragmatic and completer seizure-free rate, seizure frequency and

worsening rate, perampanel last dose and 50 percent responder rate at months 6 and 12, percentage of participants by perampanel dose titration speed, duration of treatment on perampanel, treatment-emergent adverse events (TEAEs), Serious AEs, TEAEs leading to discontinuation and severity.

Data analysis plan

Data was obtained by personnel at the study site, by reviewing medical records, seizure diaries, and records of healthcare providers' interviews with participants/caregivers at clinic visits. Data was summarized by the sponsor after study data was collected and data validation was completed. Descriptive statistics were used to calculate number and percentage for categorical variables, and mean, standard deviation, median, interquartile range, minimum and maximum, for continuous variables. Statistical analyses were performed using Statistical Analysis System software or other validated statistical software as required.

Documents

Study results

e2007-m044-512--CSR synopsis.pdf(384.7 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No