A global postmarketing observational safety study to evaluate the safety and tolerability of Fycompa (perampanel) as add-on therapy in epilepsy patients aged > 12 years

First published: 17/07/2015

Last updated: 05/12/2024

Study Finalised

Administrative details

EU PAS number

EUPAS10320

Study ID

38590

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Denmark

- [ ] France
- [ ] Israel
- [ ] Russian Federation
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

The objective of the study is to address the need for additional safety information on AEs of interest in the categories of important identified risks, important potential risks, and important missing information in the EU Risk Management Plan (RMP) for perampanelgiven as add-on therapy in patients with epilepsy.This will be achieved by assessment of events of dizziness, blurred vision, somnolence, aggression, balance disorders, ataxia, falls, unintended pregnancy, weight gain, suicidality, drug abuse, misuse, dependence, withdrawal, off-label use, skin photosensitivity, unintendedpregnancy while taking levonorgestrel-containing contraceptives, and outcomes associated with any suspected drug-drug interaction.

Study status

Finalised

Research institutions and networks

Institutions

Eisai

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Institution

Multiple centres: 100 centres are involved in the study

Contact details

Study institution contact

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Study contact

qppv_office@eisai.net

Primary lead investigator

Yvonne Lamb

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/12/2012

Actual: 05/12/2012

Study start date

Actual: 06/06/2014

Data analysis start date
Planned: 30/06/2017

Date of final study report
Planned: 31/12/2017

Actual: 24/07/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai Ltd

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

Incidence of TEAEs of interest defined as: dizziness, blurred vision, somnolence, aggression, balance disorders, ataxia, falls, unintended pregnancy, weight gain, suicidality, drug abuse, misuse, dependence, withdrawal, off-label use, skin photosensitivity, unintended pregnancywhile taking levonorgestrel-containing contraceptives, and outcomes associated with any suspected drug-drug interaction.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

FYCOMPA

Medical condition to be studied

Epilepsy

Population studied

Short description of the study population

Subjects who did not meet all of the inclusion criteria or who met any of the exclusion criteria were not eligible to receive treatment.

Inclusion Criteria

1. Male or female subjects aged ≥12 years (or as regionally appropriate) at the time of informed consent
2. Subjects prescribed perampanel for the adjunctive treatment of epilepsy within 7 days of the Screening Visit
3. Subjects who provided informed consent

Exclusion Criteria

1. Participation in another study involving administration of an investigational drug or device whilst participating in this observational study
2. Prior participation in a perampanel clinical study
3. Hypersensitivity to perampanel

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

Epilepsy patients

Estimated number of subjects

500

Study design details

Data analysis plan

The incidence of TEAEs will be summarized. The incidence of TEAEs of interest, as defined in the primary and secondary variables will be summarized or listed as appropriate. The incidence of SAEs, TEAEs leading to discontinuation, TEAEs by severity, and TEAEs by relationship to treatment will be summarized.HADS scores will be summarized.Change from baseline in weight and the proportion of patients who have at least a 5% and 10% increase in weight from baseline to EOS will be summarized.Duration of treatment and perampanel dose information will be summarized

Documents

Study results

e2007-g000-402--study-report-body-redact - PAS register.pdf (319.34 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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