An Open-Label, Observational, Prospective, Multicenter Study to Evaluate the Long-Term Efficacy and Safety of Perampanel as Monotherapy in Subjects Age 4 Years and Older with Focal Onset Seizures: PORTABLE Study

First published: 12/05/2025

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000572

EU PAS number

EUPAS1000000572

Study ID

1000000572

DARWIN EU® study

No

Study countries

☐ Japan

Study description

This is a non-interventional, prospective study in subjects with a diagnosis of FOS (with or without FBTCS), for whom the treating physician has made the decision to initiate perampanel as monotherapy.
Subjects will be identified by sites from the electronic/paper medical and pharmacy records of patients attending their usual epilepsy clinic.
The clinical decision to initiate perampanel as monotherapy will already have been made before the subject is identified for the study – ie, the decision to add perampanel is independent of the decision to enroll the subject in the study.
Before any study procedures, signed informed consent/assent form must be first obtained (or, in the case of children, the legal representative will sign consent on behalf of the subject).
Subjects will then enter into Screening Period for eligibility determination.
Demography and medical history (including epilepsy history and baseline seizure frequency based on retrospective collection from 3 months before Day 0 [day of first dose of perampanel]) will be collected.
Subjects who have provided informed consent to participate in sleep measurements will also be provided with a HARU 1 wearable device and instructed in its use for recording of baseline sleep parameters.
Subjects who are eligible will then enter the Treatment Period and perampanel monotherapy will be initiated. During the Treatment Period, data will be collected prospectively via 2 types of assessments: on site and off site.

Study status

Ongoing

Research institutions and networks

Institutions

International University of Health and Welfare Hospital, Narita

Science Tokyo

Ochiai Neurological Clinic

Tokyo Women's Medical University, Adachi Medical Center

Itami City Hospital

Toho University Sakura Hospital

TMG Asaka Medical Center

Kagoshima University

SHINJUKU NEURO CLINIC

NHO Nagasaki Medical Center

Medical corporation Seishoukai Minato Hospital

Kurume University

Yokohama Minoru Epilepsy & Developmental Clinic

Koide Clinic of Epilepsy and Neurological Disorders

Fukuoka Sanno Hospital

Contact details

Study institution contact

Naoki Akamatsu

Study contact

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Primary lead investigator

Naoki Akamatsu

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/04/2021

Actual: 30/04/2021

Study start date

Planned: 30/04/2021

Actual: 30/04/2021

Data analysis start date

Planned: 10/12/2024

Actual: 02/12/2024

Date of final study report
Planned: 23/04/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai Co., Ltd.

Study protocol

e2007-m081-515--pcs2_afterCRAB_v3_FINAL.pdf(302.11 KB)

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

UMIN000044131

UMIN-CTR PORTABLE Study

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Study design:

This is a non-interventional, prospective study in subjects with a diagnosis of FOS (with or without FBTCS), for whom the treating physician has made the decision to initiate perampanel as monotherapy.

Main study objective:

The primary objective of the study is to evaluate 24-month seizure freedom in response to perampanel monotherapy in subjects age 4 years and older with focal onset seizures (FOS) (with or without focal-to-bilateral tonic clonic seizures [FBTCS])

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Study drug and medical condition

Name of medicine

FYCOMPA

Study drug International non-proprietary name (INN) or common name

PERAMPANEL

Anatomical Therapeutic Chemical (ATC) code

(N03AX22) perampanel

perampanel

Medical condition to be studied

Epilepsy

Population studied

Short description of the study population

Inclusion Criteria

1. Male or female, age 4 years or older at the time of informed consent (in the case of minors, consent from a legal representative [eg, one parent] is required)
2. Diagnosed with FOS (with or without FBTCS) according to International League Against Epilepy (ILAE) 2017 classification
3. Newly diagnosed or recurrent epilepsy. For subjects with recurrent epilepsy, they must have relapsed at least 2 years after the end of the last antiepileptic drug (AED) treatment.
4. Subjects for whom the decision to initiate perampanel has been made, according to the judgment of the investigator

Exclusion Criteria

1. A history of receiving any AED (including AED used as rescue treatment) for

more than 2 weeks in total within 2 years before Day 0

2. Previously treated with perampanel at any time

3. A history of hypersensitivity to any of the excipients of perampanel

4. Severe hepatic impairment

5. Subjects who have participated in a study involving administration of an investigational drug/biologics or device within 4 weeks or within approximately 5 half-lives of the investigational drug/biologics,whichever is longer, before screening.

6. Not appropriate for the study according to the judgment of the investigator

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Age groups

Children (2 to < 12 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

60

Study design details

Setting

Subjects will be identified by sites from the electronic/paper medical and pharmacy records of patients attending their usual epilepsy clinic.

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Comparators

N/A

Data analysis plan

Data will be analyzed according to the Statistical Analysis Plan (SAP). Data will be analyzed using SAS or other validated statistical software as necessary.
Demography and medical history will be tabulated.

Study Endpoints

Primary Endpoint

1. Pragmatic seizure free rate at 24 months

Secondary Endpoints

1. The pragmatic seizure-free rate at 6, 12, 18, and 30 months
2. The sustained seizure-free rate at 12 and 24 months
3. Retention rate at 6, 12, 18, 24, and 30 months
4. Incidence of TEAEs
5. Change from baseline in EQ-5D-5L and PedsQL

Exploratory Endpoints

1. Change from baseline in total sleep time, sleep efficacy, sleep latency, WASO, and duration of sleep stage
2. Study drug compliance rate
3. Clinical factors to predict seizure freedom at 3, 12 and 24 months

Documents

Study report

e2007-m081-515CSRVD-red (2).pdf(653.18 KB)

Study publications

UMIN-CTR PORTABLE Study

Data management

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Yes