An Open-label, Multi-centre, Multi-national Post-marketing Non-interventional Prospective Study Evaluating Retention Rate, Seizure Control and Tolerability of Eslicarbazepine Acetate (ESL) as Adjunctive Treatment to One Baseline Antiepileptic Drug in Adult Patients With Partial-Onset Seizures With or Without Secondary Generalisation (EPOS)

First published: 08/07/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS12771

Study ID

12772

DARWIN EU® study

No

Study countries

- [ ] Czechia
- [ ] Denmark
- [ ] France
- [ ] Germany
- [ ] Ireland
- [ ] Norway
- [ ] Sweden
- [ ] United Kingdom

Study description

This was a Non-interventional Prospective Study. Centres enrolled adult patients with partial-onset seizures with or without secondary generalisation for whom the clinician had decided to initiate Eslicarbazepine Acetate (ESL) as an adjunctive therapy prior to the decision to take part in this study. Patients enrolled into the study were not sufficiently controlled with one drug licensed for the use as monotherapy in partial-onset seizures. Patients were seen at baseline and then during normal clinical visits at intervals. Patients in this study were assessed for efficacy and tolerability at baseline and then at least 3 and 6 months after the baseline.

Study status

Finalised

Research institutions and networks

Institutions

Charité-Universitätsmedizin

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Institution

Klinische und Experimentelle Epileptologie,Klinik für Neurologie

Multiple centres: 107 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Martin Holtkamp

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 20/01/2012

Study start date
Actual: 01/03/2012

Date of final study report
Actual: 13/10/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai Limited

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Efficacy and tolerability Study

Data collection methods:

Primary data collection

Main study objective:

Patients in this study will be assessed for efficacy and tolerability at baseline and then at least 3 and 6 months after the baseline.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Other- Phase IV open label study

Study drug and medical condition

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

ESLICARBAZEPINE ACETATE

Medical condition to be studied

Partial seizures

Population studied

Short description of the study population

Adult patients with partial-onset seizures with or without secondary generalisation for whom the clinician had decided to initiate Eslicarbazepine Acetate (ESL) as an adjunctive therapy prior to the decision to take part in this study.

Age groups

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 experiencing partial-onset seizures

Estimated number of subjects

219

Study design details

Outcomes

Retention Rate After 6 Months From Baseline Time Frame: Baseline (Visit 1) to Month 6 (Visit 3), Retention Rate, Total Seizure Frequency, Percentage of Seizure-Free Participants, Percentage of Responders, Percent Discontinuation of Study Treatment Due to a Lack of Efficacy, Time to Discontinuation of ESL Treatment, Quality of Life using Epilepsy Inventory (QOLIE-10), Clinical Global Impression (CGI) Severity of Illness, CGI Global Improvement, and CGI Efficacy Index.

Data analysis plan

Quantitative variables were analyzed by means of basic statistical parameters, qualitative and ordinal scaled variables were presented as absolute and relative frequency distributions. Relative frequencies were based on the number of available data, i.e. excluding missing data. No imputation methods of missing values were applied to the data. Additionally, two sided 95%-confidence intervals (CI) were calculated for the retention rates over 3 and over 6 months, respectively. For subgroup analyses, patients were classified according to gender, age (≤ 60 years, > 60 years), number of discontinued AED regimens within the last 5 years prior to baseline and most frequently used baseline AEDs (carbamazepine, levetiracetam, lamotrigine and valproate), and occurrence of adaptations of adjunct AED regimen throughout the study. All analyses were performed with the SAS® package, version 9.2 (SAS Institute, Cray, NC, USA).

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