

# 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

**Last updated:** 08/07/2016

Study

Finalised

## Administrative details

### EU PAS number

EUPAS12771

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### Study ID

12772

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## **DARWIN EU® study**

No

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### **Study countries**

-  Czechia
  -  Denmark
  -  France
  -  Germany
  -  Ireland
  -  Norway
  -  Sweden
  -  United Kingdom
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### **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.

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### **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

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## **Study start date**

Actual: 01/03/2012

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## **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

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**Study type:**

Non-interventional study

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**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

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**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

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**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

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### **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.

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### **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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients experiencing partial-onset seizures

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### **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.

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## **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 ( $\leq 60$  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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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## **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No