# European Registry of Anti-Epileptic Drug Use in Patients with Lennox-Gastaut Syndrome (LGS)

First published: 11/12/2013

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# Administrative details

EU PAS number	
EUPAS5180	
Study ID	
38601	
DARWIN EU® study	
No	
Study countries	
Austria	
Denmark	
Denmark France	

aly
pain
weden
Inited Kingdom

#### **Study description**

This is a registry study, where sites will enter patients with LGS who require a modification in anti-epileptic therapy (either the addition of another anti-epileptic drug, or the change of one drug to another). This will include patients who are started on rufinamide. Patients will be reviewed according to local practice, but it is envisaged that review will occur at approximately one month, three months and six months, and then every six months. Upon entry to the registry baseline details concerning disease severity, diagnosis, prior therapy, and developmental assessment will be recorded. On each subsequent visit the patient (usually through their caregiver) will be asked about current medication, general seizure profile, any seizures deemed to be of medical significance, tolerability, AEs (including suicidal-related events), and healthcare resource utilisation.

#### **Study status**

Finalised

## Research institutions and networks

## **Institutions**

## Eisai

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Multiple centres: 49 centres are involved in the study

## Contact details

### **Study institution contact**

Makarand Bagul EUMedInfo@eisai.net

Study contact

EUMedInfo@eisai.net

## Primary lead investigator

**EU Medical Information** 

**Primary lead investigator** 

# Study timelines

Date when funding contract was signed

Actual: 01/05/2008

Study start date

Actual: 30/07/2008

#### Data analysis start date

Actual: 01/08/2011

#### Date of interim report, if expected

Planned: 01/12/2013

#### **Date of final study report**

Planned: 01/03/2017 Actual: 05/09/2016

# Sources of funding

• Pharmaceutical company and other private sector

# More details on funding

Eisai Limited

# 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:**

Human medicinal product

Disease /health condition

#### Study type:

Non-interventional study

#### Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

#### **Data collection methods:**

Primary data collection

#### Main study objective:

Evaluation of safety during the use of rufinamide and other anti-epileptic drugs

# Study Design

#### Non-interventional study design

Cohort

# Study drug and medical condition

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

**RUFINAMIDE** 

#### **Anatomical Therapeutic Chemical (ATC) code**

(N03A) ANTIEPILEPTICS

**ANTIEPILEPTICS** 

#### Medical condition to be studied

Lennox-Gastaut syndrome

# Population studied

#### Short description of the study population

Patients (aged ≥4 years) with Lennox-Gastaut Syndrome (LGS) who required a modification in anti-epileptic therapy (either the addition of another AED or the change of one drug to another); including patients who were already receiving rufinamide.

#### Age groups

Children (2 to < 12 years)

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

Lennox-Gastaut Syndrome Patients

# Study design details

#### **Outcomes**

Safety during the use of rufinamide and other anti-epileptic drugs: Evaluation of the incidence of seizures of medical significance (including status epilepticus, new / worsening of seizure types and withdrawal seizures) during exposure to anti-epileptic drugs, including rufinamide, in patients with LGS, Long term use of rufinamide, and other anti-epileptic drugs: Evaluation, within the constraints of this population, of the impact on maturation and development that anti-epileptic drugs, including rufinamide, has on the LGS population, seizure control in LGS patients, including those taking rufinamide and other anti-epileptic drugs, assessment of healthcare resource utilisation.

#### Data analysis plan

Seizure profile assessments (including seizures of medical significance, withdrawal seizures, and a generic seizure frequency scale) will be collected at each visit. Seizure data will be summarised using descriptive statistics and graphical displays of longitudinal data. If applicable, longitudinal models or regression models will be used to evaluate changes in seizure variables over time and by subgroups. Safety will be evaluated through the collection of AEs, and detailed information through structured questions on AEs of special interest (including suicidal-related events), and reasons for discontinuation of anti-epileptic drugs. Contrasting of AEs by anti-epileptic drug and combination will be on an ad hoc basis. Incidence rates of AEs will be displayed and Kaplan-Meier plots for key AEs will be presented. Developmental assessment (height and weight) and healthcare resource utilisation will also be performed.

## **Documents**

#### **Study results**

Final abstract Rufinamide Study 401-redact - PAS register.pdf (80.45 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)**

Disease registry

Other

## Data sources (types), other

Prospective patient-based data collection

# Use of a Common Data Model (CDM)

## **CDM** mapping

No

# Data quality specifications

# Unknown Check completeness Unknown

## **Check stability**

**Check conformance** 

Unknown

## **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No