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

First published: 11/12/2013

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Study Finalised

Administrative details

EU PAS number

EUPAS5180

Study ID

38601

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Denmark
- [ ] France
- [ ] Germany

- [ ] Italy
- [ ] Spain
- [ ] Sweden
- [ ] United 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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Institution

Multiple centres: 49 centres are involved in the study

Contact details

Study institution contact

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Study contact

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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

Estimated number of subjects

225

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

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

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No