Post-marketing surveillance of long term administration of Inovelon tablets in patients with Lennox-Gastaut syndrome (INO01T)

First published: 08/08/2014

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Study Ongoing

Administrative details

EU PAS number

EUPAS7225

Study ID

28041

DARWIN EU® study

No

Study countries

☐ Japan

Study description

Prospective, multicenter practice based post marketing surveillance study of patients with Lennox-Gastaut syndrome who have been prescribed Inovelon (rufinamide).

Study status

Ongoing

Research institutions and networks

Institutions

Eisai

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Institution

Contact details

Study institution contact

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Study contact

qppv_office@eisai.net

Primary lead investigator

Yvonne Lamb

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/04/2013

Actual: 26/04/2013

Study start date
Planned: 26/04/2013

Actual: 26/04/2013

Date of final study report
Planned: 30/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Main study objective:

Post marketing surveiilance to determine the incidence of ADRs, including the incidence of skin disorders, hypersensitivity reactions and central nervous system related adverse events.The efficacy of long-term administration

Study drug and medical condition

Name of medicine

INOVELON

Medical condition to be studied

Lennox-Gastaut syndrome

Population studied

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)

Estimated number of subjects

300

Study design details

Data analysis plan

Descriptive analysis

Data management

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