

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

First published: 08/08/2014

Last updated: 05/12/2024

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

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Yvonne Lamb qppv_office@eisai.net

Study contact

qppv_office@eisai.net

Primary lead investigator

Yvonne Lamb

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 surveillance 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