E2090-E044-501: A Retrospective database Study of the Prescribing of Zonismaide in UK General Practice: A Drug Utilisation Study as Part of Post-Marketing Safety Surveillance

First published: 03/11/2016

Last updated: 05/12/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49298

EU PAS number

EUPAS14611

Study ID

49298

DARWIN EU® study

No

Study countries

United Kingdom

Study description

A drug utilisation study, conducted in the Clinical Practice Research Datalink (CPRD) in the paediatric population from 6 to 17 years of age to evaluate whether recommendations in the SmPC regarding dosing and risk mitigation strategies are being adhered to by general practitioners.

Study status

Finalised

Research institutions and networks

Institutions

Eisai

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Louise Watson

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 31/05/2016

Study start date

Planned: 15/08/2016

Actual: 15/08/2016

Date of final study report

Planned: 30/12/2016

Actual: 08/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eisai Ltd

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To provide information as to whether recommendations in the product information are being adhered to with regard to the paediatric population and in

order to provide evidence of the effectiveness of the routine risk minimisation measures through a retrospective database study

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective database study

Study drug and medical condition

Name of medicine

ZONEGRAN

Medical condition to be studied

Epilepsy

Population studied

Short description of the study population

The study participants included children and adolescents aged 6-18 years who had at least one prescription for zonisamide from 2013 to 2016, using the Clinical Practice Research Datalink GOLD database.

Age groups

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Special population of interest

Other

Special population of interest, other

Epilepsy patients

Estimated number of subjects

500

Study design details

Data analysis plan

This study will utilise descriptive methods to summarise the key outcomes used to evaluate clinical care and prescribing for children taking Zonisamide. Descriptive summaries will be provided for all paediatric patients who have at least one prescription of Zonisamide, and then further stratified into groups A, B and C, depending on the presence of an epilepsy diagnosis within the patient's medical record. No comparisons will be made between such groups, nor will any formal comparison testing be undertaken. Additionally as this is a descriptive drug utilisation study, no testing of statistical hypotheses, statistical modelling or other multivariate analyses will be performed.

Documents

Study results

e2090-e044-501-abstract-redact - PAs register.pdf(86.24 KB)

Data management

Data source(s)

Clinical Practice Research Datalink

Data sources (types)

Electronic healthcare records (EHR)

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