Risks of arrhythmias reporting with antiepileptics including Lamotrigine: a pharmacovigilance study in VigiBase®

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45560

EU PAS number

EUPAS45559

Study ID

45560

DARWIN EU® study

No

Study countries

☐ France

Study status

Ongoing

Research institutions and networks

Institutions

Toulouse University Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

François Montastruc

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/02/2022

Study start date
Actual: 02/02/2022

Date of final study report
Planned: 08/04/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Study not financed

Study protocol

Study protocol_Risks of arrhythmias Antiepileptics.pdf(232.26 KB)

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

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The aim of this study is to compare the risks of arrhythmias with lamotrigine compared with other anti-epileptics.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case/Non-case study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(N03AX09) lamotrigine

lamotrigine

Medical condition to be studied

Arrhythmia supraventricular

Conduction disorder

Ventricular arrhythmia

Cardiac arrest

Population studied

Age groups

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

7000

Study design details

Outcomes

Risk of declaring an arrhythmia

Data analysis plan

The data will be extracted from VigiBase(R). Using a case/non-case design, we will perform univariate logistic regression to estimate the odds ratios (RORs) with their 95% confidence intervals (CI). Reporting odds ratios (RORs) are the odds of exposure among reported cases of arrhythmias relative to the odds of exposure among reported non-cases. Sensitivity analyzes will be performed: First, restrict the analyzes to the reports of physicians. Second, carry out temporal analyzes every 5 years from 1994. Third, carry out analyzes just before the publication of the FDA alert on March 3, 2021.Fourth, analyzes will be performed separately on the four MedDRA high-level terms (HLTs) mentioned in the “case and non-case definitions” section. Fifth, the serious

criteria will be analyzed compared to the non-serious ones. Finally, analyzes will be carried out by stratifying the data according to age (18 to 44, 45 to 64, 65 to 74 and over 75) or sex (male or female).

Data management

ENCePP Seal

Conflicts of interest of investigators

EUPAS45559-45555.pdf(111.63 KB)

Composition of steering group and observers

EUPAS45559_steering group.pdf(232.26 KB)

Signed code of conduct

ENCePPCoCAnnex3_DeclarationofcompliancewiththeENCePPCodeofConduct-signé-signé.pdf(131.04 KB)

Signed code of conduct checklist

ENCePPCoCAnnex2_ChecklistofCodeofConduct-signé.pdf(197.16 KB)

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